

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)
_____)

MDL No. 2419
Dkt. No 1:13-md-2419 (FDS)
(Leave to File Granted 1/7/2014)

THIS DOCUMENT RELATES TO:)

Suits Identified in the Exhibit to the)
Tennessee Defendants' Contemporaneously-)
Filed Motion to Dismiss)
_____)

The Tennessee Defendants' Memorandum of Law in Support of
Their Motion to Dismiss Global Claims

Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC"), Howell Allen Clinic, a Professional Corporation ("Howell Allen"), John W. Culclasure, M.D. ("Dr. Culclasure"), Debra V. Schamberg, R.N. ("Ms. Schamberg"), Specialty Surgery Center, Crossville, PLLC ("SSC"), Kenneth R. Lister, M.D. ("Dr. Lister"), and Kenneth Lister, M.D., P.C. ("Dr. Lister's Practice") (collectively "the Tennessee Defendants"), file this Memorandum in Support of their contemporaneously-filed Motion to Dismiss Global Claims Against Tennessee Health Care Providers, pursuant to Fed. R. Civ. P. 12(b)(6) and Local Rule 7.1.

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STATEMENT OF THE CASE

These health care liability actions¹ arise from the fungal meningitis outbreak caused by contaminated, preservative-free, methylprednisolone acetate (“MPA”) manufactured by the New England Compounding Pharmacy, Inc. d/b/a the New England Compounding Center (“NECC”).

NECC sold contaminated MPA to health care providers, including STOPNC and SSC. Physicians caring for patients at those facilities, who had no knowledge or reason to know of the contamination, relied entirely on NECC’s representations as to the quality of its product and administered the MPA to patients during epidural steroid injection procedures. The Plaintiffs allege that the contaminated medication caused sickness and even death in patients across the country.

STOPNC, Howell Allen, Dr. Culclasure, and Ms. Schamberg

STOPNC is a licensed ambulatory surgery center located in Nashville, Tennessee, that unknowingly received contaminated MPA from NECC. Physicians at STOPNC administered the MPA to patients.

Howell Allen, a neurosurgical group in Nashville, owns a 50% interest in STOPNC and staffed STOPNC pursuant to a management contract.

Dr. Culclasure, a board-certified anesthesiologist, is the Medical Director of STOPNC and an employee of Howell Allen. He performed epidural steroid injection procedures at STOPNC using MPA obtained from NECC. He also participated in the decision to purchase MPA from NECC for use at STOPNC.

¹ In 2011, Tennessee’s Health Care Liability Act, Tenn. Code Ann. § 29-26-101, *et seq.*, broadly redefined “medical malpractice” claims as “health care liability actions.”

Debra Schamberg, a registered nurse, is an employee of Howell Allen and the Facility Director of STOPNC. With Dr. Culclasure, she decided to purchase MPA from NECC for use at STOPNC when faced with other suppliers on backorder.

STOPNC, Howell Allen, Dr. Culclasure, and Ms. Schamberg have been named, in various combinations, in suits filed by or on behalf of 117 patients for alleged injuries related to the injection of contaminated MPA at STOPNC. These suits include, for the most part, the same or similar “common” causes of action.

SSC, Dr. Lister, and Dr. Lister’s Practice

SSC is a licensed ambulatory surgery center in Crossville, Tennessee, that received contaminated MPA from NECC.²

Dr. Lister, a board-certified anesthesiologist, is an owner of SSC. He performed epidural steroid injections procedures at SSC using NECC MPA. He also participated in the decision to purchase MPA from NECC for use at SSC.

Dr. Lister is the sole owner and employee of Kenneth Lister, M.D., P.C.³

SSC has been named in suits filed by or on behalf of 24 patients for alleged injuries arising from the administration of contaminated MPA from NECC. Dr. Lister has been named as a defendant in 11 of those suits, and Dr. Lister’s Practice has been named in five (5) of those 11 suits. Like the suits against STOPNC, Howell Allen, Dr. Culclasure, and Ms. Schamberg, the suits against SSC, Dr. Lister, and Dr. Lister’s Practice make the same or virtually the same “common” claims.

² SSC is a separate and distinct entity from STOPNC. The relationship between the two facilities is limited to their representation by the same counsel. However, Tennessee Plaintiffs assert the same theories of liability against all Defendants.

³ The claims against Dr. Lister’s Practice are for vicarious responsibility for Dr. Lister’s actions.

Master Complaint and Responsive Pleadings

On November 5, 2013, the Plaintiffs' Steering Committee filed Master and "form" Short Form Complaints in the MDL.⁴ On November 7, 2013, the Court ordered defendants to file responses to the Master Complaint by January 10, 2014.⁵

At the December 13, 2013, status conference, the Court expressed its plan to consider motions to dismiss "global" claims (claims common to all or a substantial number of complaints) made against defendants. The Court set a deadline of January 10, 2014, for filing of motions to dismiss these global claims. These Tennessee Defendants, facing the same claims in scores of complaints, contemporaneously file their Motion to Dismiss, challenging the legal sufficiency of all common claims asserted against them.⁶ This memorandum of law addresses the insufficiency of the legal claims in "global" fashion, as the Court directed at the December 13, 2013, status conference.⁷

The Tennessee Defendants intend for their contemporaneously-filed Motion to Dismiss and this Memorandum in Support to apply to all claims against STOPNC, Howell Allen, Dr. Culclasure, and Ms. Schamberg, and to claims against SSC, Dr. Lister, and Dr. Lister's Practice, as the Tennessee Plaintiffs attempt to assert the same non-viable legal theories against all the Tennessee Defendants.⁸

⁴ [Dkts. 545, 546].

⁵ [Dkt. 567].

⁶ The Tennessee Defendants also contemporaneously file on January 10, 2014, (1) a Motion to Dismiss identifying cases with pre-suit notice deficiencies as required by the Court's December 23, 2013, Order [Dkt. 723] and (2) a Motion for Summary Judgment (or, alternatively, a Motion to Dismiss) complaints that fail to comply with the requirement that health care liability plaintiffs file a certificate of good faith with the original complaint.

⁷ The Tennessee Defendants will file case-specific dispositive motions, including those raising statute of limitations defenses in individual cases, at a later date, as directed by the Court.

⁸ In the Exhibit to their Motion to Dismiss, the Tennessee Defendants have identified the individual claims to which the below grounds for dismissal apply.

SUMMARY OF THE ARGUMENT

With no concern for individual patients, and no regard for scores of health care providers across the United States, NECC manufactured and distributed contaminated MPA. Unfortunately, this clear culpable conduct by NECC led to predictable efforts of plaintiffs' lawyers to expand the ranks of solvent potential defendants.

The pending complaints attempt to substitute a call for compensation – “all involved must pay” – for the law that defines legal responsibility. As demonstrated below, the claims made by the Plaintiffs are not valid as a matter of law under the law of Tennessee. In addition, the pleadings themselves, marked by labels, conclusions, and formulaic recitations of the elements of various causes of action, fail to identify facts to support the allegations.⁹

The Plaintiffs make nine (9) “global” claims against these Tennessee Defendant health care providers:

1. Negligence
2. Product Liability
3. Tennessee Consumer Protection Act
4. Medical Battery
5. Informed Consent
6. Civil Conspiracy
7. Vicarious Liability¹⁰
8. “Special Duty”¹¹
9. Health Care Liability.

The first eight (8) claims should be dismissed for failure to state a claim upon which relief should be granted. The ninth claim, the Plaintiffs' “health care liability

⁹ See *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

¹⁰ Responsibility for the actions of their alleged agent, NECC.

¹¹ That the Defendants owed the patients a duty to protect them from intentional harms by NECC.

actions,” are addressed by a separate Motion to Dismiss, pursuant to the Court’s December 23, 2013, Order.¹²

Tennessee Health Care Liability Act

In 2011, the Tennessee General Assembly broadly redefined “medical malpractice” actions as “health care liability actions.” After October 1, 2011, *any* suit in Tennessee against a health care provider claiming injury “related to the provision of health care services” is a “health care liability action,” which *must* be brought consistent with the Tennessee Health Care Liability Act¹³, regardless of the labels a plaintiff applies to the causes of action asserted. Plaintiffs *cannot* – as the Plaintiffs here baldly attempt to do – recast a health care liability action as another cause of action simply by designating it as something else in the complaint.¹⁴

The Plaintiffs claim injury related to injections of contaminated medications, which is obviously “related to the provision of health care services.” Accordingly, the Plaintiffs must proceed consistent with the requirements of the Health Care Liability Act for a “health care liability action.”

Requirements of Health Care Liability Act

In each “health care liability action,” the Plaintiffs must comply with the pre-suit notice and filing requirements of the Health Care Liability Act, particularly (1) providing

¹² [Dkt. 723]. These claims fail due to non-compliance with Tennessee’s pre-suit requirements applicable to all health care liability actions.

¹³ TENN. CODE ANN. § 29-26-101, *et seq.*

¹⁴ The sponsoring legislator described the intent of the bill as: “It is advantageous in the minds of some plaintiffs to keep [their lawsuit] out from under the health care provider statutes, make a cause of action look like something it isn’t at its core, so you spend most of your time at the outset trying to define what the cause of action is. We’re hopeful that this statute will obviate some of that and reduce some of that time and expense.” *available at*

http://tnga.granicus.com/MediaPlayer.php?view_id=196&clip_id=4266&meta_id=81904 (discussion beginning at 1:04:00).

pre-suit notice, meeting both content and temporal requirements, and (2) filing a certificate of good faith with the original complaint.

Any complaint not preceded by the requisite pre-suit notice or that did not include a certificate of good faith (certifying the merit of the claim) with the original complaint must be dismissed.^{15 16}

The Health Care Liability Act also explicitly establishes the burden of proof and indispensable elements of a health care liability action. The Plaintiffs bring claims under various theories and labels that are plainly inconsistent with the statutory burden of proof or elements of a health care liability action. These must be dismissed.

For instance, the Plaintiffs attempt to plead this health care liability action as a product liability action with strict liability, even though the Health Care Liability Act places a three (3) part burden of proof on the claimant, and expressly prohibits a presumption of liability. The Plaintiffs' product liability claims – clearly contrary to the controlling Health Care Liability Act – must be dismissed.

Likewise, the Plaintiffs' Tennessee Consumer Protection Act claims must be dismissed because they are inconsistent with the Health Care Liability Act.

The Plaintiffs' ordinary negligence claims must be dismissed as the Health Care Liability Act eliminates ordinary negligence claims where the claim is for injury related to the provision of health care services.¹⁷

¹⁵ TENN. CODE ANN. §§ 29-26-121, -122.

¹⁶ The Tennessee Defendants identify cases with deficient pre-suit notices in a separate motion to dismiss as required by the Court's December 23, 2013, Order. [Dkt. 723].

¹⁷ See *Parker v. Portland Nursing & Rehab*, No. M2011-02633-COA-R9-CV, 2012 WL 376800, at *4, *5, n. 4 (Tenn. Ct. App. Aug. 30, 2012) ("[a]s Plaintiff correctly states, claims for ordinary negligence and medical malpractice are separate and distinct causes of action as discussed in *Estate of French v. Stratford House*, 333 S.W.3d 546 (Tenn. 2011). Both parties note that the passage of the Tennessee

Finally, the claims for medical battery, “failure to warn,” and breach of a “special duty” are claims that *must* be brought pursuant to the Tennessee Health Care Liability Act’s specific provision governing lack of informed consent claims (Tenn. Code Ann. § 29-26-118). The Plaintiffs’ failure to do so mandates dismissal of those claims.

Product Liability

In addition to being clearly contrary to the controlling requirements of the Tennessee Health Care Liability Act, the Plaintiffs’ product liability claims against these health care providers fail as a matter of law under analogous Tennessee precedent. Tennessee courts have consistently held that defendants who use a product incidental to the provision of services are not *sellers* of the product subject to strict product liability.

Other states (*23 of the 25 that have considered this specific question*) and respected tort commentators agree that physicians and other health care providers providing health care services are not *sellers* subject to strict liability in tort.^{18 19}

Law and logic dictate that health care providers providing professional services are not *sellers* of medications, syringes, cotton balls, or gauze used incidental to the services they provide, and, thus, are not subject to product liability actions as

Civil Justice Act of 2011 ended this distinction and created a new cause of action of a ‘health care liability’ claim”).

¹⁸ W. Prosser and W. Page Keeton, *Prosser and Keeton on Torts*, § 104, at 720 (5th Ed. 1984) (“Hospitals, medical doctors, and other professionals who provide health care services have not generally been held strictly liable even when, in the course of rendering health care services, defective products are transmitted. They are not regarded as the kind of enterprisers, akin to the producer of mass products, that can conveniently bear the costs of accidents attributable to defective things used and transmitted. Moreover, the principal thing bargained for is not the product transmitted but the professional services of the defendant.”).

¹⁹ Admittedly, Tennessee courts have not considered the precise issue in this exact factual context. But, the statutory language and analogous case law – combined with the overwhelming decisions of other states – make clear where Tennessee’s law is on this issue.

guarantors of the safety of the product. The product liability claims against these health care providers are not viable as a matter of law and must be dismissed.

Tennessee Consumer Protection Act

The Plaintiffs cannot recover for personal injury or wrongful death under the plain language of the TCPA²⁰ and under Tennessee case law interpreting the TCPA²¹. Additionally, Tennessee courts have held that medical malpractice claims (now called health care liability actions) “may not be recast as consumer protection act claims.”²²

Therefore, the Plaintiffs’ TCPA claims must be dismissed.

Medical Battery Claims

An essential element of a medical battery claim in Tennessee is that the patient did not authorize the performance of the procedure.²³ Here, the Plaintiffs do not allege that the procedure was unauthorized. In fact, the Plaintiffs allege the exact opposite – that they consented to the performance of the procedure.²⁴

Failure to allege facts to sustain a required element of the claim – that the procedure was unauthorized – mandates dismissal of the Plaintiffs’ medical battery claims.

Lack of Informed Consent Claims

There is no institutional duty to obtain informed consent.²⁵ Only the health care provider recommending and performing the procedure can be liable for failure to obtain

²⁰ TENN. CODE ANN. § 47-18-109.

²¹ *Riddle v. Lowe’s Home Centers*, 802 F. Supp. 2d 900, 908-09 (M.D. Tenn. 2011); *Kirksey v. Overton Pub*, 804 S.W.2d 68, 73 (Tenn. Ct. App. 1990).

²² *Constant v. Wyeth*, 352 F. Supp. 2d 847, 854 (M.D. Tenn. 2003).

²³ *Blanchard v. Kellum*, 975 S.W.2d 522, 524 (Tenn. 1998).

²⁴ Master Compl. ¶ 297.

²⁵ *Bryant v. HCA Health Servs. of Tenn.*, 15 S.W.3d 804, 807-10 (Tenn. 2000).

informed consent.²⁶ Thus, the claims against STOPNC, Howell Allen, Dr. Culclasure (in the cases where he did not perform the injections), Ms. Schamberg, SSC, and Dr. Lister's Practice for informed consent must be dismissed under clear Tennessee precedent.

Civil Conspiracy Claims

The Plaintiffs' civil conspiracy claims fail as a matter of law because (1) they are time-barred and (2) the facts pled do not support the required elements of the claim.

First, the statute of limitations for a civil conspiracy claim accrues at the time of the last overt act in furtherance of the conspiracy.²⁷ Here, the Plaintiffs allege acts constituting a conspiracy that, at the latest, ended in September 2012. Thus, any claim for civil conspiracy filed after September 2013 (at the latest) must be dismissed as time-barred.²⁸

Second, Tennessee law requires a plaintiff to allege specific facts to support each element of a claim for civil conspiracy.²⁹ The Plaintiffs conclusively plead, as the unlawful act, that the Tennessee Defendants conspired with NECC to violate a non-existent or inapplicable Massachusetts regulation. Obviously, the Tennessee Defendants could not unlawfully conspire to violate a non-existent or inapplicable regulation.

Additionally, the Plaintiffs fail to plead facts to establish the essential element of intentional conduct to defraud the patients – common purpose.

²⁶ *Id.*

²⁷ *Swafford v. Memphis Individual Practice Ass'n*, No. 02A01-9612-CV-00311, 1998 WL 281935, at *4 (Tenn. Ct. App. 1998).

²⁸ TENN. CODE ANN. § 28-3-104.

²⁹ *Kincaid v. SouthTrust Bank*, 221 S.W.3d 32, 38 (Tenn. Ct. App. 2006) (internal citations omitted).

Lastly, the Plaintiffs plead no facts to sustain a causal nexus between the alleged conspiracy to avoid patient-specific prescriptions and the injury from contaminated medications.

These fatal deficiencies mandate dismissal.

Vicarious Liability for the Actions of NECC

The Plaintiffs make the novel claim (novel and devoid of supporting law or facts) that NECC was acting as the agent of these Tennessee health care providers when NECC manufactured contaminated medications that caused injury. But, the Plaintiffs allege no facts to establish control over NECC's actions, an essential factor when evaluating an alleged agency relationship.³⁰ These allegations simply do not state a claim upon which relief can be granted and must be dismissed.

"Special Duty" Claims

The Plaintiffs allege that the Tennessee Defendants had a "special" duty to protect their patients from NECC intentionally contaminating the medications. However, Tennessee law simply does not impose a "special duty" on health care providers to protect their patients from intentional actions of third parties. Furthermore, the Plaintiffs do not allege facts to sustain such a claim, and it must be dismissed.

Conclusion

The Plaintiffs have asserted a statutorily-defined health care liability action, nothing more, nothing less. The attempts to obscure the governing law by imaginative pleading cannot succeed under the plain language of the Health Care Liability Act:

³⁰ *McInturff v. Battle Ground Academy of Franklin*, No. M2009-00504-COA-R3-CV, 2009 WL 4878614, at *3 (Tenn. Ct. App. Nov. 5, 2009).

"Health care liability action" means any civil action, including claims against the state or a political subdivision thereof, alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, regardless of the theory of liability on which the action is based.³¹

For that reason, and the reasons below, each of the Plaintiffs' creative – but non-viable – legal claims must be dismissed.

STANDARD OF REVIEW

Rule 12(b)(6) of the Federal Rules of Civil Procedure governs motions to dismiss for failure to state a claim upon which relief can be granted. Rule 12(b) provides that a defense of "failure to state a claim upon which relief can be granted" may be raised by motion.³²

This Court has previously explained the standard in considering a Rule 12(b)(6) motion to dismiss:

On a motion to dismiss, the Court "must assume the truth of all well-plead[ed] facts and give plaintiff the benefit of all reasonable inferences therefrom." *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). To survive a motion to dismiss, the plaintiff must state a claim that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). That is, "[f]actual allegations must be enough to raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556). Dismissal is appropriate if the complaint's well-pleaded facts do not "possess enough heft to show that plaintiff is entitled to relief." *Ruiz Rivera v. Pfizer Pharm., LLC*, 521 F.3d 76, 84 (1st Cir. 2008) (quotations and original alterations omitted).³³

³¹ TENN. CODE ANN. § 29-26-101(a)(1) (emphasis added).

³² Fed. R. Civ. P. 12(b).

³³ *Rando v. CVS Pharmacy, Inc.*, No. 13-11130-FDS, 2013 WL 6489947, at *2 (D. Mass. Dec. 9, 2013) (citations and alterations in original); *U.S. v. Takeda Pharm. Co. Ltd.*, No. 10-11043-FDS, No. 11-10343-FDS, No. RTH, 2012 WL 5398564, at *3 (D. Mass. Nov. 1, 2012).

This Court has also held:

To survive a motion to dismiss under the Rule, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). A pleading that merely offers "labels and conclusions" or a "formulaic recitation of the elements of a cause of action" is insufficient. *Id.* at 555, 127 S.Ct. 1955.³⁴

Pursuant to Fed. R. Civ. P. 12(b)(6), the Tennessee Defendants move to dismiss each of the Plaintiffs' causes of action, as specifically identified and explained below, for failure to state a claim upon which relief can be granted.

LAW AND ARGUMENT

Relevant Legislative Background

In a comprehensive reform of the state's tort system in 2011, the Tennessee General Assembly³⁵ passed the "Tennessee Civil Justice Act of 2011."³⁶ The Civil Justice Act significantly reformed a tort plaintiff's ability to recover from Tennessee defendants.^{37 38}

³⁴ *U.S. v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48, 61 (D. Mass. 2010).

³⁵ Hereinafter, at times, referred to simply as the "Legislature."

³⁶ House Bill No. 2008/ Senate Bill No. 1522 (signed by the governor on 6/16/11), *available at* <http://www.tn.gov/sos/acts/107/pub/pc0510.pdf>.

³⁷ See Elder, John W., and Walker, Joshua R., *The Tennessee Civil Justice Act of 2011: What a Difference a Day Made*, TENN. B. J., Vol. 47, No. 8 (Aug. 2011), *available at* http://www.tba.org/sites/default/files/journal_archives/2011/TBJ0811.pdf.

³⁸ The Civil Justice Act included, among other reforms:

- Changes to the Products Liability Act of 1978 to limit the ability to assert causes of action against and recover from "sellers" of products (TENN. CODE ANN. § 29-28-106)
- Changes to the Products Liability Act that limit the recovery of punitive damages (TENN. CODE ANN. § 29-28-104)
- Narrowing of the Tennessee Consumer Protection Act limiting causes of action to only the specific acts prohibited in the statute (TENN. CODE ANN. § 47-18-104)
- Changes to the Medical Malpractice Act that expanded the universe of cases to which previous reforms (pre-suit notice and certificate of good faith requirements) apply (TENN. CODE ANN. §§ 29-26-101, -121, -122)

At common law, a “medical malpractice action” was defined as any claim bearing “a substantial relationship to the rendition of medical treatment by a medical professional, or concerning medical art, science, training, or otherwise....”³⁹ This vague standard resulted in substantial litigation over whether a claim fit the definition.

As one (1) element of the 2011 broad-based reform, the Tennessee Legislature, with the Health Care Liability Act⁴⁰ (hereinafter, at times, the “Act”), changed the name of a “medical malpractice action” to a “health care liability action” and codified a broad definition:

“Health care liability action” means any civil action, including claims against the state or a political subdivision thereof, alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, regardless of the theory of liability on which the action is based.⁴¹

By redefining “medical malpractice” claims as “health care liability actions” and codifying a broadened definition, the Legislature expanded the universe of cases to which the law governing these cases applies.⁴² The Legislature did so to eliminate costly and time-consuming disputes over whether a case bears a “substantial relationship to the rendition of medical treatment, making it a “medical malpractice” case subject to specific pre-suit notice, filing, and pleading requirements.⁴³ The Legislature

-
- Imposition of specific limitations on non-economic and punitive damages in all tort cases (TENN. CODE ANN. § 29-39-101, *et seq.*).

³⁹ *Estate of French v. Stratford House*, 333 S.W.3d 546, 570 (Tenn. 2011).

⁴⁰ TENN. CODE ANN. § 29-26-101, *et seq.*

⁴¹ TENN. CODE ANN. § 29-26-101(a)(1) (emphasis added); *Cunningham v. Williamson Cnty. Hosp. Dist.*, 405 S.W.3d 41, 45, n.1, n. 2 (Tenn. 2013) (recognizing change in statutory language from “medical malpractice” to “health care liability action”).

⁴² *Id.*

⁴³ See Comments of (sponsoring) Senator Norris, May 12, 2011, responding to questions about intent of bill: “It is advantageous in the minds of some plaintiffs to keep it out from under the health care provider statutes, make a cause of action look like something it isn’t at its core, so you spend most of your time at the outset trying to define what the cause of action is. We’re hopeful that this statute will obviate some of that and reduce some of that time and expense,” *available at*

also broadened the definition to abolish any distinction between ordinary negligence and medical malpractice claims against health care providers.⁴⁴

Notwithstanding this clear legislative mandate, the Plaintiffs allege eight (8) causes of action outside the statutorily-defined “health care liability action.” All claims against health care providers from October 1, 2011-forward alleging injuries related to medical care, including the claims alleged by the Plaintiffs, are “health care liability actions” and *must* proceed consistent with the 2011 Health Care Liability Act.⁴⁵

I. The Plaintiffs’ claims not pled as “health care liability actions” consistent with the requirements of the Tennessee Health Care Liability Act must be dismissed for failure to state a claim upon which relief can be granted.

A. Tennessee statutes must be interpreted consistent with their plain meaning and the legislative intent.

“The cardinal canon of statutory construction requires the courts to ascertain and to carry out the General Assembly’s intent.”⁴⁶ “A statute’s intent is reflected in the statute’s words, and, therefore, [courts] must focus initially on the words of the statute.”⁴⁷ “When the words of the statute are clear and unambiguous, [courts] need not

http://tnga.granicus.com/MediaPlayer.php?view_id=196&clip_id=4266&meta_id=81904, (discussion beginning at 1:04:00). The bill passed in the Senate that day, was passed in the House on May 20, 2011, and was signed by the governor June 16, 2011.

⁴⁴ See *Parker v. Portland Nursing & Rehab*, No. M2011-02633-COA-R9-CV, 2012 WL 3776800, at *4, *5, n. 4 (Tenn. Ct. App. Aug. 30, 2012) (“[a]s Plaintiff correctly states, claims for ordinary negligence and medical malpractice are separate and distinct causes of action as discussed in *Estate of French v. Stratford House*, 333 S.W.3d 546 (Tenn. 2011). . . . Both parties note that the passage of the Tennessee Civil Justice Act of 2011 ended this distinction and created a new cause of action of a ‘health care liability’ claim”).

⁴⁵ Title 29, Chapter 26 of the Tennessee Code has historically been referred to as the “Medical Malpractice Act.” With the amendments in 2011 to broaden the statute’s applicability and redefine the cause of action, the section is now referred to as the “Health Care Liability Act.” See, e.g., *Barnett v. Tennessee Orthopaedic Alliance*, No. M2011-01978-COA-R3-CV, 2012 WL 4166994, at *6 (Tenn. Ct. App. Sept. 19, 2012.).

⁴⁶ *Norma Faye Pyles Lynch Family Purpose LLC v. Putnam Cnty.*, 301 S.W.3d 196, 213 (Tenn. 2009) (internal citations omitted).

⁴⁷ *Id.*

look beyond the statute, but rather, [courts] must simply enforce the statute as it is written.”⁴⁸

Courts applying Tennessee statutes must give effect to the legislative intent without broadening the application of the statute beyond its intended scope.⁴⁹ Courts must give the language of a statute its “natural and ordinary meaning.”⁵⁰ If the statutory language is clear and unambiguous, the court’s inquiry should stop there.⁵¹

“When a statute is clear, [Tennessee courts] apply the plain meaning without complicating the task, and simply enforce the written language.”⁵² A statute should be interpreted to preclude any part from being “inoperative, superfluous, void, or insignificant.”⁵³ ⁵⁴ Courts should likewise recognize and consider the Legislature’s intent that a term be defined broadly where, as here, the Legislature has amended a section to broaden a definition.⁵⁵

B. Any claim for injury related to the provision of health care services, regardless of the theory of liability asserted, must be brought as a “health care liability action.”

"Health care liability action" means any civil action. . . alleging that a health care provider or providers. . . have caused an injury related to the provision of. . . health care services. . . regardless of the theory of liability on which the action is based.⁵⁶

⁴⁸ *Id.*

⁴⁹ *Barker v. State*, No. M2011-01381-SC-R11-PC, 2013 WL 4768309, at *2 (Tenn. Sept. 6, 2013) (internal citations omitted).

⁵⁰ *Lee Med., Inc. v. Beecher*, 312 S.W.3d 515, 526 (Tenn. 2010).

⁵¹ *Keen v. State*, 398 S.W.3d 594, 610 (Tenn. 2012).

⁵² *Hunt v. Genie Indus., Inc.*, 202 S.W.3d 99, 101-02 (Tenn. 2006).

⁵³ *Tidwell v. Collins*, 522 S.W.2d 674, 676-77 (Tenn. 1975).

⁵⁴ Also of note, although applied in the context of implying a private cause of action in a regulatory scheme, Tennessee follows the maxim that, where a statute expressly provides a particular remedy, a court should be hesitant to read other remedies into it. *Brown v. Tennessee Title Loans, Inc.*, 328 S.W.3d 850, 860 (Tenn. 2010) (citing *Transam. Mortgage Advisors, Inc. v. Lewis*, 444 US 11, 19 (1979)).

⁵⁵ See *Lee Med., Inc.*, 312 S.W.3d at 531.

⁵⁶ TENN. CODE ANN. § 29-26-101(a)(1) (emphasis added).

“Health care services” is defined as “care by health care providers,” including “physicians, nurses, licensed practical nurses, pharmacists, pharmacy interns or pharmacy technicians under the supervision of a pharmacist, orderlies, certified nursing assistants, advance practice nurses, physician assistants, nursing technicians, and other agents, employees, and representatives of the provider.”⁵⁷ The definition of “health care services” even extends to activities not specific to bedside care, including staffing of facilities.⁵⁸

The plain language of the Act brings any claim against a health care provider related to the provision of health care squarely within the requirements of the Act.⁵⁹

Applying the plain meaning of the statutory language to the factual allegations in the complaints demonstrates that the Plaintiffs allege the Defendant health care providers caused injury as a result of the administration of medication, which is undoubtedly “related to the provision of...health care services”⁶⁰:

- “As a direct and proximate result of the Clinic Related Defendants [*sic*] wrongful conduct, the Plaintiffs were administered contaminated products by the Clinic Related Defendants, causing serious injuries to the Plaintiffs, and at times death.”⁶¹
- “Joseph Pellicone received epidural steroid injections on August 13, 2012, and August 28, 2012 at Saint Thomas Outpatient Neurosurgical Center in Nashville, Tennessee. Joseph Pellicone received the epidural injections for treatment of worsening back and leg pain. One or more of the injections he received came from a contaminated lot of MPA purchased from NECC. The contaminated lots were subsequently recalled by NECC.

⁵⁷ *Id.* at -101(a)(2).

⁵⁸ *Id.*

⁵⁹ *Haley v. State*, No. E2012-02484-COA-R3-CV, 2013 WL 5431998, at *11, n. 1 (Tenn. Ct. App. Sept. 25, 2013) (“Tennessee Code Annotated section 29-26-101 now defines *most all cases occurring in a medical context* as ‘health care liability actions’”) (emphasis added).

⁶⁰ TENN. CODE ANN. § 29-26-101.

⁶¹ Master Compl. ¶ 206.

Joseph Pellicone contracted fungal meningitis as a result of receiving the contaminated MPA.”⁶²

- “The Plaintiffs’ injections of MPA caused them various injuries and medical conditions including, but not limited to, fungal meningitis, localized spinal or paraspinal infections (i.e. [s/c] epidural abscesses, arachnoiditis, phlegmon, etc.), anxiety, depression, and complications associated with lumbar punctures. The Plaintiffs’ injections of MPA also caused them to undergo various unnecessary and painful medical treatments including, but not limited to, lumbar punctures, blood patches, hospitalizations, MRIs, and CT scans.”⁶³

The label chosen by the author of a complaint does not dictate the substantive law governing the claim.⁶⁴ Because the complaints all allege injury related to the provision of health care, they are undoubtedly “health care liability actions” subject to the requirements of the Act, regardless of the labels attached to the claims or the theories of liability the Plaintiffs assert.^{65 66}

⁶² *Pellicone, et al. v. Ameridose, et al.*, No. 1:13-cv-12916-FDS, Compl. ¶¶ 164-69 (hereinafter, “*Pellicone Compl.*”). The Tennessee Defendants cite to the *Pellicone* Complaint (in addition to the Master Complaint) throughout the brief as it is representative of the over 100 complaints filed against the Tennessee Defendants.

⁶³ *Barger, et al. v. Ameridose, et al.*, No. 1:13-cv-12619-FDS, Compl. ¶ 7 (hereinafter “*Barger Compl.*”).

⁶⁴ *Estate of French v. Stratford House*, 333 S.W.3d at 557.

⁶⁵ TENN. CODE ANN. § 29-26-101 (“any civil action, including claims against the state or a political subdivision thereof, alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, *regardless of the theory of liability on which the action is based*”) (emphasis added).

⁶⁶ Notably, even before the Legislature broadened the definition of “medical malpractice” in 2011, Tennessee courts applying the common law definition of “medical malpractice” consistently found cases alleging negligence related to, and injury caused by, the administration of medication, to be medical malpractice cases governed by the Medical Malpractice Act. See, e.g., *Sharkey v. O’Toole*, No. M2009-0112-COA-R3-CV, 2010 WL 3293925, at *1-*6 (Tenn. Ct. App. Aug. 19, 2010) (analyzing case in which the physician allegedly prescribed Haldol to a patient with a known Haldol allergy as medical malpractice case); *Taylor v. Jackson-Madison Cnty. Gen. Hosp. Dist.*, No. W2005-02471-COA-R3-CV, 2006 WL 2423456, at *1 (Tenn. Ct. App. Aug. 23, 2006) (analyzing case of allegedly negligent use of antibiotic, causing allergic reaction, as medical malpractice case); *Foster v. St. Joseph Hosp.*, No. W2003-00522-COA-R3, 2004 WL 1717679, at *1 (Tenn. Ct. App. July 30, 2004) (characterizing claim that defendant health care providers gave medication to patient to which she was allergic as claim for medical malpractice); *Howse v. State*, 994 S.W.2d 140, 140-41 (Tenn. Ct. App. 1999) (analyzing case of allegedly negligent administration of earwax medication, causing allergic reaction, as medical malpractice case); *Crowe v. Craig*, No. 02A01-9612-CV-00297, 1997 WL 359261, at *1-*6 (Tenn. Ct. App. June 27, 1997) (analyzing case of allegedly negligent administration of pain medication to patient with allergy to pain medication as medical malpractice case); *Oaks v. State*, No. 03-A01-9104BC00129, 1991 WL 260668, at *1 (Tenn. Ct. App. Dec. 12, 1991) (“[t]his is a medical malpractice suit...”; “By way of preface, we note

C. Claims pled inconsistent with the Health Care Liability Act, or that fail to comply with the procedural requirements of the Act, should be dismissed for failure to state a claim upon which relief can be granted.

Because the Plaintiffs allege health care liability actions, the law at Tenn. Code Ann. § 29-26-101, *et seq.* applies to these complaints.⁶⁷ ⁶⁸ This includes the requirements that the Plaintiffs provide pre-suit notice compliant with the Act⁶⁹ and file a certificate of good faith with the original complaint, certifying its merit⁷⁰.

In addition to these requirements, the Act also sets out the Plaintiffs' burden of proof in a health care liability action⁷¹ (including specific proof requirements for claims alleging failure to inform the patient of the risks of the procedure⁷²). The Plaintiffs must prove *by expert testimony* (1) the applicable standard of acceptable professional practice, (2) a breach of that standard, and (3) injury caused by the breach.⁷³

The Plaintiffs' claims that fail to comply with these requirements, or fail to allege the required elements, should be dismissed for failure to state a claim upon which relief can be granted.

that it was the Oakses' theory that Mr. Oaks was negligently administered a drug known as heparin by employees of the Medical Center although it was known from a previous confinement at the Medical Center that Mr. Oaks was allergic to this drug").

⁶⁷ TENN. CODE ANN. § 29-26-101 ("[a]ny such civil action or claim is subject to this part regardless of any other claims, causes of action, or theories of liability alleged in the complaint").

⁶⁸ The Act also identifies (1) applicable evidentiary rules, (2) the statute of limitations, (3) recoverable damages, and (4) other procedural requirements. TENN. CODE ANN. §§ 29-26-115, -116, -117, -119, -121, and -122.

⁶⁹ TENN. CODE ANN. § 29-26-121.

⁷⁰ TENN. CODE ANN. § 29-26-122.

⁷¹ TENN. CODE ANN. § 29-26-115.

⁷² TENN. CODE ANN. § 29-26-118.

⁷³ TENN. CODE ANN. §§ 29-26-115, -118.

1. **Any complaint that did not satisfy the pre-suit notice requirement, or that was not filed with a certificate of good faith should be dismissed.**

In every health care liability action, the plaintiff must provide written, pre-suit notice of the potential claim, which must comply with the requirements set out in Tenn. Code Ann. § 29-26-121. A motion to dismiss is the appropriate avenue to challenge non-compliance with the notice provisions.⁷⁴

In *Myers v. AMISUB (SFH), Inc.*, the Tennessee Supreme Court stated:

The essence of Tennessee Code Annotated section 29-26-121 is that a defendant be given notice of a medical malpractice claim before suit is filed. . . . The requirements of pre-suit notice of a potential claim under Tennessee Code Annotated section 29-26-121 and the filing of a certificate of good faith under Tennessee Code Annotated section 29-26-122 are **fundamental** to the validity of the respective statutes and dictate that we construe such requirements as **mandatory**.⁷⁵

Failure to comply with the pre-suit notice requirements mandates dismissal of non-compliant complaints.^{76 77}

Likewise, the clear statutory language requires that a plaintiff file a certificate of good faith with the original complaint asserting a health care liability action.⁷⁸ Failure to file a certificate of good faith with the complaint mandates dismissal with prejudice.⁷⁹

⁷⁴ *Myers v. AMISUB (SFH), Inc.*, 382 S.W.3d 300, 307 (Tenn. 2012).

⁷⁵ *Id.* at 309 (emphasis added).

⁷⁶ See also *Stevens v. Hickman Cmty. Health Care Servs., Inc.*, No. M2012-00582-SC-S09-CV, 11-12 (Tenn. Nov. 25, 2013).

⁷⁷ The Tennessee Defendants have identified complaints with section -121 and section -122 deficiencies in separate pleadings.

⁷⁸ TENN. CODE ANN. § 29-26-122 (“[i]n any health care liability action in which expert testimony is required by § 29-26-115, the plaintiff or plaintiff’s counsel shall file a certificate of good faith with the complaint. If the certificate is not filed with the complaint, the complaint shall be dismissed, as provided in subsection (c), absent a showing that the failure was due to the failure of the provider to timely provide copies of the claimant’s records requested as provided in § 29-26-121 or demonstrated extraordinary cause”).

⁷⁹ *Dunlap v. Laurel Manor Health Care, Inc.*, No. E2012-02432-COA-R3-CV, 2013 WL 4680494, at *1 (Tenn. Ct. App. Aug. 29, 2013) (affirming dismissal of case for failure to file certificate of good faith after court deemed complaint one for medical malpractice).

Those complaints not originally filed with a certificate of good faith should be dismissed with prejudice.⁸⁰

2. The Plaintiffs' claims under the Tennessee Products Liability Act of 1978 fail to state a claim upon which relief can be granted because, as a claim for liability without fault, it is a claim directly contrary to the express burden of proof requirements of the Health Care Liability Act.

The Plaintiffs attempt to plead this health care liability action as a claim for strict product liability against these Defendant health care providers, asserting they are “sellers” under the Tennessee Products Liability Act of 1978.⁸¹

First, the Defendant health care providers are not “sellers” of the medications they administer. Consistent with the rule of law in virtually all states, the Plaintiffs cannot maintain a product liability claim against these Defendant health care providers.⁸²

Second, the Plaintiffs' claim for strict product liability is expressly contrary to the Health Care Liability Act. Thus, the Court should dismiss the Plaintiffs' product liability claim as the Plaintiffs fail to, and cannot, plead the claim consistent with the Act.

Tenn. Code Ann. § 29-26-115 requires that the *plaintiff prove* by expert testimony (1) the recognized standard of acceptable professional practice, (2) that the defendant breached the standard, and (3) that the breach proximately caused the injury.⁸³

⁸⁰ As discussed in detail in the pleading identifying suits subject to dismissal for failure to file a certificate of good faith, the filing of a certificate of good faith with the Short Form Complaints, which is an amended complaint, is not sufficient to remedy the violation of Tenn. Code. Ann. § 29-26-122. TENN. CODE ANN. § 29-26-122 (requiring the certificate of good faith to be filed “with the complaint”) (emphasis added); *Vaughn v. Mountain States Health Alliance*, No. E2012-01042-COA-R3-CV, 2013 WL 817032, at *2 (Tenn. Ct. App. March 5, 2013) (holding that deficiencies in complying with -121 and -122 cannot be cured by amendment); Supplemental Order on Pending Motions to Dismiss, for Summary Judgment, and to Amend, [Dkt. 725] (noting that the Short Form Complaints are amendments to the Plaintiffs' original complaints).

⁸¹ Master Compl. Count IX.

⁸² This additional ground for dismissal is addressed in Section II., A. below,

⁸³ *Id.*

Tenn. Code Ann. § 29-26-115(c) states explicitly that, “[i]n a health care liability action as described in subsection (a)⁸⁴, there shall be no presumption of negligence on the part of the defendant[.]”⁸⁵ Section (d) reiterates this point, requiring that the jury be instructed in a health care liability action that “the claimant has the burden of proving, by a preponderance of the evidence, the negligence of the defendant” and that “injury alone does not raise a presumption of the defendant’s negligence.”⁸⁶

By pleading their health care liability action as a product liability claim, the Plaintiffs attempt to hold the Tennessee Defendants strictly liable.⁸⁷ However, strict liability – liability *without* an express finding of fault – is directly contrary to the Health Care Liability Act’s explicit prohibition against presumptions of negligence and the Act’s statutory burden of proof.

The Plaintiffs’ product liability action should be dismissed for failure to state a claim upon which relief can be granted. The only relief the Plaintiffs can be granted in this case is by pleading and proving their case consistent with the requirements of the Health Care Liability Act, not the conflicting provisions of the Products Liability Act.^{88 89}

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⁸⁴ Subsection (a) sets out the elements of proof in a health care liability action.

⁸⁵ TENN. CODE ANN. § 29-26-115.

⁸⁶ *Id.*

⁸⁷ Master Compl. ¶ 328 (“The Tennessee Healthcare Providers Defendants are strictly liable...”).

⁸⁸ See *Budding v. SSM Healthcare Sys.*, 19 S.W.3d 678 (Mo. 2000) (holding that Missouri’s health care liability act precluded bringing product liability claim against defendant health care provider where implant used by defendant was defective; “by using the words ‘any action’ in sec. 538.225.1, the legislature clearly demonstrated its intent that the statute not only apply to a negligence action but to a products liability action as well”).

⁸⁹ See *Thomas v. Shipka*, 818 F.2d 496, 503-04 (6th Cir. 1987) (affirming district court’s dismissal of claim where plaintiff attempted to bring claim against city official outside the framework of § 1983 and pursuant to other statute, holding § 1983 provides exclusive remedy; “Plaintiff seeks to establish a separate independent constitutional claim under § 1331 based on the same facts and the same substantive constitutional provisions which give rise to her claim under § 1983. The only justification which plaintiff provides for the recognition of a separate theory is that it would arguably allow her to take advantage of

3. The Plaintiffs' claims under the Tennessee Consumer Protection Act fail to state a claim upon which relief can be granted because they seek relief inconsistent with the Health Care Liability Act.

Some Plaintiffs assert a claim pursuant to the Tennessee Consumer Protection Act ("TCPA") against the Defendant health care providers.⁹¹ The Master Complaint alleges:

- The Clinic Related Defendants made false representations, participated in unfair competition, or committed deceptive acts, in violation of Tennessee's consumer protection laws.⁹²
- The Clinic Related Defendants failed to provide accurate information and misrepresented other information about the medications to patients as part of the consenting process.⁹³

These allegations amount to nothing more than a creative – yet improper – attempt to plead a health care liability action for lack of informed consent as a different cause.⁹⁴

This attempt fails under Tennessee law.

First, the Plaintiffs simply cannot bring a claim under the TCPA for personal injury or wrongful death.^{95 96}

Second, the Plaintiffs cannot bring a claim under the TCPA against a health care provider arising from the provision of medical services.^{97 98}

the six year Ohio statute of limitations which applies to actions arising under statutes. We find this argument to be disingenuous at best"); *Corey v. New York Stock Exchange*, 691 F.2d 1205, 1212-13 (6th Cir. 1982) (dismissing case as plaintiff attempted to assert causes of action inconsistent with federal Arbitration Act, holding Arbitration Act is exclusive remedy available).

⁹⁰ Additionally, as discussed in Section II., A. below, the product liability claim fails to state a claim upon which relief can be granted because the Defendant health care providers are not "sellers."

⁹¹ Master Compl. Count IV.

⁹² Master Compl. ¶ 245.

⁹³ Master Compl. ¶¶ 247-52.

⁹⁴ See TENN. CODE. ANN. § 29-26-118.

⁹⁵ *Kirksey v. Overton Pub, Inc.*, 804 S.W.2d 68, 73 (Tenn. Ct. App. 1990); *Akers v. Prime Succession of Tennessee*, 387 S.W.3d 495, 509-10 (Tenn. 2012); *Riddle v. Lowe's Home Ctrs.*, 802 F. Supp. 2d 900, 909 (M.D. Tenn. 2011).

⁹⁶ This additional ground for dismissal is discussed in Section II., B., 1. below

Third, like the product liability claim, based on the plain language of the Health Care Liability Act, the Plaintiffs cannot maintain an action under the TCPA.

Tenn. Code. Ann. § 29-26-101(a)(1) clearly states that the Act governs any claims, regardless of the theory of liability asserted. “Any claim” means any claim, including a claim under the TCPA.⁹⁹ By pleading their health care liability action as a consumer protection claim, the Plaintiffs attempt to modify both the elements of proof¹⁰⁰ and the damages available upon proper proof^{101, 102}.

Specifically, Tenn. Code Ann. § 29-26-118 – not the TCPA – sets out the pleading and proof requirements for a claim that the Defendant health care providers did not provide appropriate information to patients about the procedures.¹⁰³ Section 29-26-118 requires the Plaintiffs to prove, by expert testimony (1) the recognized standard of acceptable professional practice for disclosure of risks associated with the recommended procedure, (2) a departure from that standard of acceptable professional practice, and (3) causation. The Plaintiffs’ TCPA claims fall woefully short of alleging the elements required by § 29-26-118.

⁹⁷ *Constant*, 352 F. Supp. 2d at 854 (“[t]his court agrees with the reasoning of these courts that medical malpractice claims may not be recast as consumer protection act claims”); *Proctor v. Chattanooga Orthopaedic Grp., P.C.*, 270 S.W.3d 56, 59 (Tenn. Ct. App. 2008) ([physicians are immune from suit under the TCPA] “when the plaintiff’s allegations concern the actual provision of medical services”) (quoting *Constant v. Wyeth*, 352 F. Supp. 2d 847, 853-54 n. 10 (M.D. Tenn. 2003)).

⁹⁸ This additional ground for dismissal is addressed in Section II., B., 2. below

⁹⁹ TENN. CODE. ANN. § 29-26-101(a)(1).

¹⁰⁰ Compare TENN. CODE ANN. § 29-26-118 and TENN. CODE ANN. § 29-26-115 with TENN. CODE ANN. § 47-18-104 (defining deceptive and unfair practices).

¹⁰¹ Compare TENN. CODE ANN. § 29-26-119 (describing recoverable damages) with TENN. CODE ANN. § 47-18-109(a)(3) (allowing for the recovery of treble damages).

¹⁰² *Constant*, 352 F. Supp. 2d at 854 (“[t]his court agrees with the reasoning of these courts that medical malpractice claims may not be recast as consumer protection act claims”).

¹⁰³ TENN. CODE ANN. § 29-26-118 (“[i]n a health care liability action, the plaintiff shall prove by evidence as required by § 29-26-115(b) that the defendant did not supply appropriate information to the patient in obtaining informed consent (to the procedure out of which plaintiff’s claim allegedly arose) in accordance with the recognized standard of acceptable professional practice in the profession and specialty, if any, that the defendant practices in the community in which the defendant practices and in similar communities”).

Therefore, because the Plaintiffs fail to allege the required elements of a health care liability action, attempting to recast it as a TCPA claim, the Plaintiffs' TCPA claims should be dismissed for failure to state a claim upon which relief can be granted.

4. The Plaintiffs' claims for ordinary negligence fail to state a claim upon which relief can be granted because they fail to allege a violation of the recognized standard of acceptable professional practice.

Some Plaintiffs plead claims for ordinary negligence, presumably attempting to avoid the requirements of the Act.¹⁰⁴ One of the primary purposes of Tenn. Code Ann. § 29-26-101, in defining "health care liability action," was to eliminate the distinction between ordinary negligence claims and medical malpractice claims when, like here, a plaintiff alleges an injury related to the provision of health care services.¹⁰⁵ *Any and all* claims for injury related to the provision of health care services must allege a breach of the recognized standard of acceptable professional practice, not just a breach of the ordinary standard of care.¹⁰⁶ The Plaintiffs' ordinary negligence claims fail to plead the recognized standard of acceptable professional practice.

Therefore, the Plaintiffs' ordinary negligence claims fail to state a claim upon which relief can be granted and must be dismissed as a distinct cause of action.¹⁰⁷

¹⁰⁴ Master Compl. Count III.

¹⁰⁵ TENN. CODE ANN. § 29-26-101; *see Parker*, No. M2011-02633-COA-R9-CV, 2012 WL 3776800, at *4, *5, n. 4 ("[a]s Plaintiff correctly states, claims for ordinary negligence and medical malpractice are separate and distinct causes of action as discussed in *Estate of French v. Stratford House*, 333 S.W.3d 546 (Tenn. 2011)....Both parties note that the passage of the Tennessee Civil Justice Act of 2011 ended this distinction and created a new cause of action of a 'health care liability' claim").

¹⁰⁶ TENN. CODE ANN. § 29-26-101.

¹⁰⁷ *See Parker*, No. M2011-02633-COA-R9-CV, 2012 WL 3776800, at *4, *5, n. 4.

5. The Plaintiffs' claims for medical battery, "failure to warn," and breach of a "special duty" fail as a matter of law because they are inconsistent with the Health Care Liability Act.

Some Plaintiffs make (1) a claim for medical battery, asserting that the Defendant health care providers injected the Plaintiffs without their consent.¹⁰⁸ They also attempt to (2) bring a claim for "failure to warn" the patients of the risks of the medications¹⁰⁹ and (3) breach of a "special duty" in failing to warn patients of, or protect patients from, the foreseeable risk that NECC would intentionally contaminate medication¹¹⁰. These claims allege, in essence, that the Defendant health care providers did not provide appropriate information to the Plaintiffs in connection with their epidural steroid injections.

As discussed above, the Health Care Liability Act applies to these health care liability actions. As such, Tenn. Code Ann. § 29-26-118 – *not* the Plaintiffs' common law cause of action – governs the elements of proof in claims asserting inadequate disclosure of risks associated with medical treatment.

The Plaintiffs have failed to plead the required elements to state a claim under § 29-26-118 in alleging their claims for (1) medical battery, (2) "failure to warn," and (3) breach of a "special duty." Therefore, those claims must be dismissed for failure to state a claim upon which relief can be granted under the Health Care Liability Act.

¹⁰⁸ Master Compl. Count VII, ¶ 297 ("and did not consent to the injection of contaminated drugs into their bodies").

¹⁰⁹ Master Compl. ¶¶ 300-03.

¹¹⁰ *Pellicone* Compl. ¶¶ 191-99.

II. In the alternative, certain of the Plaintiffs' claims fail to state a claim upon which relief can be granted for the additional reasons discussed below.

As discussed in Section I. above, the Plaintiffs must proceed pursuant to the requirements of the Health Care Liability Act. To the extent the Plaintiffs bring claims that are inconsistent with the Act, or that fail to allege the elements required by the Act, those claims must be dismissed.

To the extent the Court determines the Plaintiffs' claims for product liability, violation of the Tennessee Consumer Protection Act, medical battery, lack of informed consent, civil conspiracy, vicarious liability for the wrongdoing of NECC, and violation of a "special duty" do not warrant dismissal under the Act, the Court should still dismiss those claims as they fail to state a claim upon which relief can be granted for the additional reasons described below.

A. The Plaintiffs' claims under the Tennessee Products Liability Act of 1978 fail to state a claim upon which relief can be granted because health care providers are not "sellers."

The Plaintiffs allege that the Tennessee Defendants are strictly liable under the Tennessee Products Liability Act of 1978,¹¹¹ as "sellers" of a defective product. The Plaintiffs, however, conveniently ignore the fact that no relevant statutory or case law establishes these health care providers as *sellers* of the medications used.

The Products Liability Act generally prohibits plaintiffs from pursuing products liability claims against any seller other than the manufacturer.¹¹² But, when the manufacturer is judicially-declared insolvent or is not subject to service of process¹¹³,

¹¹¹ TENN. CODE ANN. § 29-28-101, *et seq.*

¹¹² TENN. CODE ANN. § 29-28-106.

¹¹³ There are three additional exceptions to the general rule not applicable to the present case. TENN. CODE ANN. § 29-28-106(1)-(3).

plaintiffs may pursue product liability claims against the “seller” of the defective product.¹¹⁴ A seller is defined as “any individual or entity engaged in the business of selling a product.”¹¹⁵

First and foremost, the Tennessee Defendants, health care providers, are not alleged to be “engaged in the business of selling a product” as contemplated by the Products Liability Act.¹¹⁶

Second, Tennessee courts have specifically concluded that providers of professional services are not sellers of the tangible products utilized during the delivery of professional services.¹¹⁷

In addition to Tennessee’s professional services precedent, *23 of the 25 states that have addressed the issue* (and the District of Columbia) have specifically held that health care providers are not sellers of the items consumed during the provision of health care services.^{118 119}

¹¹⁴ TENN. CODE ANN. § 29-28-106(4)-(5).

¹¹⁵ TENN. CODE ANN. § 29-28-102(7); *see generally* *Parker v. Warren*, 503 S.W.2d 938, 945 (Tenn. Ct. App. 1973); *Delta Refining Co. v. Procon, Inc.*, 552 S.W.2d 387, 389 (Tenn. Ct. App. 1976).

¹¹⁶ TENN. CODE ANN. § 29-28-102(7).

¹¹⁷ *Parker*, 503 S.W.2d at 945; *Delta Refining Co.*, 552 S.W.2d at 389 (Tenn. Ct. App. 1976).

¹¹⁸ *Ayyash v. Henry Ford Health Sys.*, 533 N.W.2d 353, 210 Mich. App. 142 (Ct. App. 1995); *Brandt v. Boston Scientific Corp.*, 792 N.E.2d 296 (Ill. 2003); *Budding v. SSM Healthcare Sys.*, 19 S.W.3d 678 (Mo. 2000); *Cafazzo v. Cent. Med. Health Servs.*, 542 Pa. 526 (1995); *Cobb v. Dallas Fort Worth Med. Ctr.-Grand Prairie*, 48 S.W.3d 820 (Tex. App. 2001); *Doyle v. Planned Parenthood of Seattle-King Cnty., Inc.*, 31 Wn. App. 126 (Wash. App. 1982); *Easterly v. Hosp. of Texas, Inc.*, 772 S.W.2d 211 (Tex. App. 1989); *Eby v. Milton S. Hershey Med. Ctr.*, 31 Pa. D. & C.4th 121 (Pa. C.P. 1996); *Femrite v. Abbott Northwestern Hosp.*, 568 N.W.2d 535 (Minn. App. 1997); *Ferguson v. EBI Med. Sys.*, No. 527663, 1995 WL 462438 (Conn. Super. Aug. 1, 1995); *Foster v. Memorial Hosp. Ass’n*, 219 S.E.2d 916 (W. Va. 1975); *Goldfarb v. Teitelbaum*, 149 A.D.2d 566 (N.Y. App. Div. 1989); *Greenberg v. Michael Reese Hosp.*, 83 Ill.2d 282 (Ill. 1980); *Hector v. Cedars-Sinai Med. Ctr.*, 180 Cal. App. 3d 493 (Cal. App. 1986); *Herrick v. Middlesex Hosp.*, No. CV030100932, 2005 WL 1760785 (Conn. Super. June 27, 2005); *Hoff v. Zimmer*, 746 F. Supp. 872 (W.D. Wis. 1990); *Hollander v. Sandoz Pharmaceuticals Corp.*, 289 F.3d 1193 (10th Cir. 2002); *Hoven v. Kelble*, 79 Wis.2d 444 (Wis. 1977); *Howell v. Spokane & Inland Empire Blood Bank*, 114 Wn. 2d 42 (Wash. 1990); *Iacangelo v. Georgetown Univ.*, No. 05-2086(PLF) (AK), 2006 WL 4391359 (Mag. D.D.C. Oct. 11, 2006); *In re Breast Implant Prod. Liability*, 331 S.C. 540 (1998); *Johnson v. Mountainside Hosp.*, 571 A.2d 318 (N.J. Super. App. Div. 1990); *Johnson v. Sears, Roebuck & Co.*, 355 F. Supp. 1065 (E.D. Wis. 1973); *Karibjanian v. Thomas Jefferson Univ. Hosp.*, 717 F. Supp. 1081 (E.D.

This Court must (1) apply the plain language of the statute requiring that sellers be “engaged in the business of selling a product,” (2) follow Tennessee precedent recognizing that providers of professional services are not sellers of items incidental to the services, and (3) follow the overwhelming precedent across other jurisdictions directly on point, and specifically find that plaintiffs cannot maintain product liability actions against Tennessee health care providers who unknowingly use defective medications incidental to the care they provide.

Pa. 1989); *Lambert v. Charlotte Hungerford Hosp.*, 2006 WL 3491275 (Conn. Super. Nov. 2, 2006); *LaValla v. Parker*, Nos. 90-1442, 89-2949, 1991 WL 17757 (E.D. Pa. Feb. 12, 1991); *Leith v. Henry Ford Hosp.*, No. 211008, 2000 WL 33420641 (Mich. App. May 16, 2000); *McCombs v. Southern Regional Med. Ctr., Inc.*, 504 S.E.2d 747 (Ga. App. 1998); *McKenna v. Harrison Memorial Hosp.*, 960 P.2d 486 (Wash. App. 1998); *NME Hosps., Inc. v. Azzariti*, 573 So. 2d 173 (Fla. App. 1991); *North Miami General Hosp., Inc. v. Goldberg*, 520 So. 2d 650 (Fla. App. 1988); *Pantano v. Telectronics Pacing Sys., Inc.*, No. 95-CV-0753E(M), 1996 WL 107099 (W.D.N.Y. Feb. 15, 1996); *Parker v. St. Vincent Hosp.*, 919 P.2d 1104 (N.M. App. 1996); *Perlmutter v. Beth David Hosp.*, 308 N.Y. 100 (N.Y. 1954); *Pierson v. Sharp Memorial Hosp., Inc.*, 216 Cal. App. 3d 340 (Cal. App. 1989); *Pleasant v. Dow Corning Corp.*, No. 3:92-3180-17, 1993 WL 1156110 (D.S.C. Jan. 7, 1993); *Podrat v. Codman-Shurtleff, Inc.*, 384 Pa. Superior Ct. 404 (Pa. Super. 1989); *Probst v. Albert Einstein Med. Ctr.*, 440 N.Y.S.2d 2 (N.Y. App. Div. 1981); *Roberts v. Suburban Hosp.*, 532 A.2d 1081 (Md. App. 1987); *Roell v. Stryker Corp.*, No. 3:06-cv-443-HTW-LRA, 2007 WL 2783357 (S.D. Miss. Sept. 21, 2007); *Royer v. Catholic Med. Ctr.*, 144 N.H. 330 (N.H. 1999); *Samuels v. Health & Hosp. Corp.*, 432 F. Supp. 1283 (S.D.N.Y. 1977); *San Diego Hosp. Ass’n v. Superior Court*, 30 Cal. App. 4th 8, (Cal. App. 1994); *Satorius v. Proassurance Wisconsin Insurance Co.*, No. 2011AP2809, 2012 WL 5319213 (Wis. App. Oct. 30, 2012); *Shepard v. Alexian Brothers Hosp.*, 33 Cal. App. 3d 606 (Cal. App. 1973); *Shivers v. Good Shepherd Hosp., Inc.*, 427 S.W.2d 104 (Tex. Civ. App. 1968); *Silverhart v. Mount Zion Hosp.*, 20 Cal. App. 3d 1022 (Cal. App. 1971); *Simone v. Long Island Jewish Hillside Med. Ctr.*, 81 Misc. 2d 163 (N.Y. Sup. 1975); *Snyder v. Mekhjian*, 244 N.J. Super. 281 (N.J. Super. App. Div. 1990); *St. Mary Med. Ctr., Inc. v. Casco*, 639 N.E.2d 312 (Ind. App. 1994); *Tucker v. Kaleida Health*, No. 09-CV-719S., 2011 WL 1260117 (W.D.N.Y. March 31, 2011); *Vergott v. Deseret Pharmaceutical Co.*, 463 F.2d 12 (5th Cir. 1972); *Von Downum v. Synthes*, No. 12-CV-278-GKF-FHM, 2012 WL 5463900 (N.D. Okla. Nov. 8, 2012); *Weissman v. Dow Corning Corp.*, 892 F. Supp. 510 (S.D.N.Y. 1995); *Zbras v. St. Vincent’s Med. Ctr.*, 880 A.2d 999, 1002 (Conn. App. 2005); *Zelle v. Bayer Corp.*, No. FSTCV08CV094019435, 2012 WL 1435192 (Conn. Super. Feb. 2, 2012); KAN. STAT. ANN. § 60-3302(a). *Contra Saylor v. Providence Hosp.*, 680 N.E.2d 193 (Ohio App. 1996); *Skelton v. Druid City Hosp. Bd.*, 459 So.2d 818 (Ala. 1984).

¹¹⁹ Of the 25 states, Oklahoma and Mississippi’s decisions were federal court interpretations of state law.

1. Tennessee courts have consistently found that providers of services are not “sellers” of products.

In *Parker v. Warren* and *Delta Refining Co. v. Procon, Inc.*, the Tennessee Court of Appeals, interpreting § 402A of the *Restatement (Second) of Torts*¹²⁰, held that a provider of professional services is not a seller of the items used during the provision of those services.¹²¹ The rationales of *Parker* and *Delta Refining* are analogous to the professional medical services¹²² provided by the Defendant health care providers here.

a. *Parker v. Warren*

In *Parker*, carpenters used wood to construct the top two rows of bleachers at an event venue.¹²³ During a wrestling match, one of the bleacher boards broke, causing the plaintiff to fall and suffer injuries.¹²⁴ The defendants, the owner of the venue and the promoter of the wrestling event, filed a third-party complaint against the carpenters asserting products liability and breach of warranty claims.^{125 126}

The court found the third-party product liability claim against the carpenters should not go to the jury:

[T]he proof establishes the [carpenters] were not *sellers* of the lumber used in the two top rows of bleacher seats, and they were not engaged in the business of *selling* such a product. Under Restatement of Torts, Second, § 402A, strict

¹²⁰ Section 402A of the *Restatement (Second) of Torts* governs strict product liability and was adopted by Tennessee courts in *Ford Motor Company v. Lonon*, 398 S.W.2d 240, (Tenn. 1966). In 1978, § 402A was codified, with some minor changes, as Tennessee's Products Liability Act. When applying the Products Liability Act, Tennessee courts have consistently cited to cases analyzing § 402A, including *Davis v. Komatsu America Industries Corp.*, 42 S.W.3d 34, 43 (Tenn. 2001) (citing *Parker*, 503 S.W.2d 938).

¹²¹ *Parker*, 503 S.W.2d at 945; *Delta Refining*, 552 S.W.2d at 389.

¹²² Even the Tennessee Department of Revenue recognizes that health care providers are professional service providers. TENN. COMP. R. & REGS. 1320-5-1-.47 (tax rule recognizing physicians and surgeons provide professional services).

¹²³ *Parker*, 503 S.W.2d at 941.

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ Tenn. Code Ann. § 47-2-313 and § 47-2-315 govern breach of warranty claims under the Uniform Commercial Code – Sales. The analysis of whether a service provider is a seller under the U.C.C. is analogous to whether a service provider is a seller under Tennessee's Products Liability Act.

liability in tort is so limited. We therefore hold the doctrine of strict liability in tort not applicable to those third party defendants. See and compare: *Freitas v. Twin City Fisherman's Cooperative Association*, (Tex. Civ. App. 1970), 452 S.W.2d 931; *Katz v. Slade* (Mo. 1970), 460 S.W.2d 608. The trial judge correctly refused to charge the law of strict liability in tort as to the [carpenters].¹²⁷

The court reasoned that the carpenters “were not engaged in the business of selling,” and therefore, strict products liability was inapplicable.¹²⁸

b. *Delta Refining Co. v. Procon, Inc.*

In *Delta Refining*, the court considered whether a general contractor could be found strictly liable as a seller under § 402A of the *Restatement (Second) of Torts*.¹²⁹

The defendant general contractor entered into a contract with the plaintiff, under which the general contractor would purchase and install a pump at the plaintiff's facility.¹³⁰ The general contractor purchased the pump from the manufacturer and installed it.¹³¹ The bolts in the pump failed, and the pump exploded, causing a large fire.¹³² The plaintiff alleged that the general contractor was strictly liable pursuant to § 402A of the *Restatement (Second) of Torts*.¹³³

The Tennessee Court of Appeals, citing *Parker*, dismissed the plaintiff's claim for strict seller liability.¹³⁴ The court reasoned:

In the instant case, [the general contractor] did not sell the defective pump in the sense used in Restatement of Torts, 402A. It was not in the business of selling such pumps. [The general contractor] merely contracted with [the Plaintiff] to purchase and install a pump which [the manufacturer] would build according to specifications furnished by Plaintiff.¹³⁵

¹²⁷ *Parker*, 503 S.W.2d at 942, 945 (emphasis in original).

¹²⁸ *Id.*

¹²⁹ *Delta Refining*, 552 S.W.2d at 388-89.

¹³⁰ *Delta Refining*, 552 S.W.2d at 388.

¹³¹ *Id.* at 388.

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.* at 390.

¹³⁵ *Id.* at 389.

The court's rationale was that general contractors, as service providers, are "not in the business of selling," and therefore, strict products liability did not apply.¹³⁶

c. The products the Tennessee Defendants utilized were incidental to professional medical services; thus, under analogous Tennessee case law, the Tennessee Defendants are not "sellers."

As Tennessee courts have consistently held, a provider of professional services is not a seller of items consumed incidental to the provision of those professional services.¹³⁷

Here, the Plaintiffs sought professional services from the Tennessee Defendants, not the purchase of MPA.¹³⁸ Administration of MPA was incidental to the services of medical diagnosis and treatment.¹³⁹ Like the analogous carpenter building bleachers (and using lumber to do so) or general contractor installing a pump (and purchasing the pump from a third party), health care providers are not "engaged in the business of selling" the medication they administer to patients.¹⁴⁰

A conclusory statement that the Tennessee Defendants "sold" medication with no reasonable theory asserted to support such a claim is legally insufficient to state a viable claim.¹⁴¹

¹³⁶ *Id.* (emphasis added).

¹³⁷ *Parker*, 503 S.W.2d 938; *Delta Refining*, 552 S.W.2d 387.

¹³⁸ *Pellicone Compl.* ¶ 164.

¹³⁹ *Pellicone Compl.* ¶ 164-67.

¹⁴⁰ *Parker*, 503 S.W.2d 938; *Delta Refining*, 552 S.W.2d 387.

¹⁴¹ *U.S. v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48, 61 (D. Mass. 2010) (internal citations omitted).

2. Other states and commentators have, in overwhelming fashion, concluded that a product liability action against a health care provider is not viable as a matter of law.

a. Respected tort commentators reiterate the rule that product liability claims against health care providers are not viable.

i. *Restatement (Third) of Torts*

Whether to classify a health care provider as a seller for the purposes of strict products liability is not a novel issue. The *Restatement (Third) of Torts*, under the heading “Definition of ‘One Who Sells or Otherwise Distributes,’” notes, “in a strong majority of jurisdictions, hospitals are held not to be sellers of products they supply in conjunction with the provision of medical care, regardless of the circumstances.”¹⁴²

ii. A.L.R.

Similarly, an American Law Report aggregating cases, aptly titled “Liability of hospital or medical practitioner under doctrine of strict liability in tort, or breach of warranty, for harm caused by drug, medical instrument, or similar device used in treating patient,” states:

A number of courts have considered application of the related theories of strict liability in tort and breach of warranty in actions by patients against hospitals or medical practitioners for injuries suffered from medical instruments, drugs, or prostheses/implants used in treatment. Generally, attempts to apply product liability principles to what would be conventional medical malpractice actions have been unsuccessful. . . .¹⁴³

iii. Prosser and Keaton

Prosser and Keaton on Torts, a standard reference on torts, also notes:

Hospitals, medical doctors, and other professionals who provide health care services have not generally been held strictly liable even when, in the course of rendering health care services, defective products are transmitted. They are not

¹⁴² *Restatement (Third) of Torts*, Products Liability § 20, cmt. d (1998).

¹⁴³ 65 A.L.R. 5th 357.

regarded as the kind of enterprisers, akin to the producer of mass products, that can conveniently bear the costs of accidents attributable to defective things used and transmitted. Moreover, the principal thing bargained for is not the product transmitted but the professional services of the defendant.¹⁴⁴

These commentators have reached consensus on two (2) points: first, health care providers are not sellers for the purpose of strict products liability; and second, it violates public policy to impose strict products liability on health care providers.

b. The overwhelming majority of states have held that product liability claims against health care providers are not viable as a matter of law.

The state court cases of *In re Breast Implant Product Liability*¹⁴⁵, *Caffazo*¹⁴⁶, and *Ayyash*¹⁴⁷ are excellent, representative examples of the near-universal rule that health care providers cannot be held liable under a product liability theory for defective medication used when providing health care services.¹⁴⁸

i. *In re Breast Implant Product Liability*

In *In re Breast Implant Product Liability*, the relevant issues before the Supreme Court of South Carolina were:

1. May a health care provider be held strictly liable under S.C. Code Ann. § 15-73-10¹⁴⁹ for a medical device or instrument used in the course of treating a patient?

¹⁴⁴ W. Prosser and W. Page Keeton, *Prosser and Keeton on Torts*, § 104, at 720 (5th Ed.1984).

¹⁴⁵ 331 S.C. 540 (1998).

¹⁴⁶ 542 Pa. 526 (1995).

¹⁴⁷ 533 N.W.2d 353, 210 Mich. App. 142 (Ct. App. 1995).

¹⁴⁸ In addition to the specific examples of *In re Breast Implant Product Liability*, *Caffazo*, and *Ayyash*, the Tennessee Defendants attach as an Exhibit a summary of the relevant case law nationally.

¹⁴⁹ S.C. CODE ANN. § 15-73-10 states:

Liability of seller for defective product

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm caused to the ultimate user or consumer, or to his property, if
 - (a) The seller is engaged in the business of selling such a product, and
 - (b) It is expected to and does reach the user or consumer without substantial change in the condition in which it is sold
- (2) The rule stated in subsection (1) shall apply although

2. May a health care provider be held liable for the breach of implied warranties under Article II of the Uniform Commercial Code with regard to a medical device or instrument used in the course of treating a patient?
3. May a health care provider be held liable for the breach of an express warranty under Article II of the Uniform Commercial Code with regard to a medical device or instrument used in the course of treating a patient?¹⁵⁰

The court first noted that the determinative issue was whether a health care provider was a “seller” within the meaning of South Carolina’s product liability statute¹⁵¹.¹⁵² Following precedent similar to Tennessee’s own *Parker* and *Delta Refining* cases, the court determined that health care providers are not sellers, stating that “South Carolina cases, as well as persuasive authority from other jurisdictions, dictate that health care providers are not ‘sellers’ under Restatement § 402A.”¹⁵³ ¹⁵⁴

The court reasoned:

In analyzing this question, we must consider whether the essence of the transaction is the provision of a service or a product. We hold that health care providers who perform breast implant procedures are, in essence, providing a service. Although the breast implant procedure requires the use of a product, the implant, the health care provider is fundamentally and predominantly offering a service. The provider must have medical knowledge and skill to conduct the procedure. He must advise the patient of the medical consequences and must recommend to the patient the preferable type of procedure. The product may not be purchased independently of the service. One does not “buy” a breast implant procedure in the same way as one would buy a product, such as a lawnmower. At its heart, the breast implant procedure is a service and not a product.¹⁵⁵

(a) The seller has exercised all possible care in the preparation and sale of the product, and

(b) The user or consumer has not bought the product from or entered into any contractual relation with the seller.

¹⁵⁰ *In re Breast Implant Prod. Liability*, 331 S.C. at 544.

¹⁵¹ S.C. CODE ANN. § 15-73-10.

¹⁵² *In re Breast Implant Prod. Liability*, 331 S.C. at 545-46.

¹⁵³ *Id.* at 546-51.

¹⁵⁴ Tennessee codified § 402A, with minor changes, as the Tennessee Products Liability Act.

¹⁵⁵ *Id.* at 547.

The South Carolina court cited treatises finding that, “[i]n general, the courts have refused to apply the concept of strict liability in tort to a person rendering professional or nonprofessional services, where injury occurs through a defective product used by the person rendering such services, or as a result of allegedly defective services themselves.”¹⁵⁶ The court continued by noting that, when presented with the question of “whether health care providers may be held strictly liable under products liability law,” “[a]n overwhelming majority of courts have responded in the negative.”¹⁵⁷

The court concluded its analysis of other states’ law by finding “[t]here is very little authority to support finding health care providers strictly liable under products liability law.”¹⁵⁸

The Supreme Court of South Carolina thus concluded that “health care providers offer services, not products,” and that the product liability claims failed as a matter of law.^{159 160}

ii. ***Cafazzo v. Central Medical Health Services***

In *Cafazzo*, Mr. Cafazzo underwent surgery for implantation of a mandibular prosthesis.¹⁶¹ Mr. Cafazzo sued the physician who performed the surgery and the hospital where the surgery took place, alleging that the implant was defective.¹⁶² Mr. Cafazzo claimed that “all defendants sell, provide or use certain prosthetic devices,” and

¹⁵⁶ *Id.* at 547 (cite omitted).

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* at 550.

¹⁵⁹ *Id.* at 553.

¹⁶⁰ The court also dismissed the plaintiff’s breach of warranty claims under the U.C.C. *Id.*

¹⁶¹ *Cafazzo*, 542 Pa. at 529.

¹⁶² *Id.*

that they should be held strictly liable as having “provided, sold or otherwise placed [the implant] in the stream of commerce products.”¹⁶³

Similar to the case at bar, the manufacturer of the implant had filed for bankruptcy, and the plaintiffs pursued a solvent source of recovery.¹⁶⁴ The Pennsylvania Supreme Court considered whether the physician and hospital were sellers of the implant as contemplated by § 402A.¹⁶⁵ The court held that the physician and hospital were not sellers for the purposes of § 402A, and even if the physician and hospital “marketed” the prosthesis and charged more than the cost of acquisition for the item, strict liability did not apply.¹⁶⁶

The court explained:

[T]o ignore the ancillary nature of the association of product with activity is to posit surgery, or indeed any medical service requiring the use of a physical object, as a marketing device for the incorporated object. This is tantamount to deciding that the surgical skills necessary for the implantation of, e.g., mandibular prostheses, are an adjunct to the sale of the implants. Moreover, under such a theory, no product of which a patient in any medical setting is the ultimate consumer, from CT scanners to cotton balls, could escape the assignment of strict liability. Clearly, the relationship of hospital and/or doctor to patients is not dictated by the distribution of such products, even if there is some surcharge on the price of the product. . . .¹⁶⁷

The court stated that the focus of the analysis is “not on whether a separate consideration is charged for the physical material used in the exercise of medical skill, but what service is performed to restore or maintain the patient’s health.”¹⁶⁸

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Id.* at 529-30.

¹⁶⁶ *Id.* at 530.

¹⁶⁷ *Id.* at 531.

¹⁶⁸ *Id.* at 532 (internal citations omitted).

The court concluded that the implant and all other material objects involved in the operation were incidental to the primary activity, medical service.¹⁶⁹ As a result, the court held that the health care providers were “not sellers, providers, suppliers or distributors of products” under § 402A.¹⁷⁰

Following its holding that health care providers were not sellers under § 402A, the court continued its analysis into the sensible public policy rationales for declining to impose strict liability on health care providers. The court noted that imposing strict liability against health care providers would not incentivize safer products, stating:

As the Superior Court correctly pointed out, the safety of the product depends on the judgment of those connected to the research, development, manufacture, marketing and sale of the product. Moreover, the safety testing and licensing for use of medical devices is a responsibility specifically undertaken by the federal government. Therefore, imposing liability for a poorly designed or manufactured product on the hospitals and doctors who use them on the assurances of the FDA is highly unlikely to effect changes of this sort. . . .¹⁷¹

The court concluded, from a public policy perspective, imposing strict liability on health care providers would result in an increase in insurance rates with no corresponding improvement in patient care.¹⁷² As a result, the Pennsylvania Supreme Court refused to impose strict liability against health care providers.¹⁷³

iii. *Ayyash v. Henry Ford Health Systems*

In *Ayyash*, the plaintiff fell down a flight of stairs and broke her jaw.¹⁷⁴ The chief of the oral surgery department at Henry Ford Health Systems implanted a Vitek

¹⁶⁹ *Id.* at 533.

¹⁷⁰ *Id.* at 534.

¹⁷¹ *Id.* at 535-36 (internal citation omitted) (emphasis added).

¹⁷² *Id.* at 535-36.

¹⁷³ *Id.* at 534 (noting that health care providers would be forced to pass this cost along to patients and their insurers).

¹⁷⁴ *Ayyash*, 533 N.W.2d 353, 210 Mich. App. 142.

prosthesis into her jaw.¹⁷⁵ The FDA approved the prosthesis in 1983, but, in 1992, the implants were recalled after Vitek filed for bankruptcy.¹⁷⁶ The plaintiff sued the surgeon and the hospital under various product liability theories since the manufacturer enjoyed the shield of the automatic bankruptcy stay.¹⁷⁷

The issue of first impression before the Michigan Court of Appeals was “whether a plaintiff, injured by an admittedly defective medical implant placed in her body during surgery by her physician (at a hospital) may maintain a strict liability claim against her doctor and the hospital for the injuries caused by the defective implant.”¹⁷⁸

The *Ayyash* court joined the majority and characterized the transaction as a service. The court reasoned:

Because the primary function of physicians and hospitals is to provide care, not to manufacture or distribute products, those economic theories that underlie the imposition of strict liability upon makers and sellers of products do not justify the extension of strict liability to those who provide medical services. It is reasonable to conclude that the vast majority of patients would bear the increased costs associated with such an impractical imposition of liability upon the medical profession for the benefit of a few who for some reason (here bankruptcy) may not be able to obtain recovery from the manufacturer of the defective product. This Court would be remiss if it failed to express its compassion for plaintiff, and others like her, who may be left without a remedy for injuries caused by a defective medical implant. However, this Court should not and will not let its compassion in this case persuade it to adopt a rule of law that would likely cause greater long-term harm to more patients and the medical profession by an ill-advised adoption of strict liability against health care providers.

Further, whereas imposing strict liability on manufacturers arguably may promote greater care in manufacturing safer products, imposing strict liability on hospitals and physicians would not. Rather, to do so would place an unrealistic burden on the physicians and hospitals of this state to test or guarantee the tens of thousands of products used in hospitals by doctors.

¹⁷⁵ *Id.* at 143.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 145.

Because imposing liability without fault in such cases would ultimately hurt rather than help patients and their doctors, we affirm the lower court's grant of summary disposition.¹⁷⁹

c. Analogous Tennessee case law, commentators, and the overwhelming majority of persuasive authority from other states dictate that the Plaintiffs' claims for product liability against these health care providers fail as a matter of law.

As analogous Tennessee case law demonstrates, tort commentators reiterate, and 23 of the 25 states considering the issue have held, health care providers are not "sellers" subject to strict liability claims.¹⁸⁰ This novel theory lacks logical and legal support and simply cannot serve as a means for plaintiffs to shift NECC's liability to parties who had no hand in the manufacture of this product. The Court, respectfully, cannot and should create a cause of action in Tennessee for product liability against health care providers in this context where no reasonable prior precedent (or, frankly, any rule of law from other jurisdictions) supports such a cause of action.

The Plaintiffs' products liability claims fail to state a claim upon which relief can be granted and should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6).

B. The Plaintiffs' Tennessee Consumer Protection Act claims fail as a matter of law and must be dismissed.

The Plaintiffs' Tennessee Consumer Protection Act ("TCPA") claims should be dismissed because they seek relief inconsistent with the Health Care Liability Act.¹⁸¹

In the alternative, the Plaintiffs' TCPA claims fail on two additional, independent grounds.

¹⁷⁹ *Id.* at 146-47.

¹⁸⁰ *Parker*, 503 S.W.2d 938; *Delta Refining*, 552 S.W.2d 387; *Restatement (Third) of Torts, Products Liability* § 20, cmt. d (1998); 65 A.L.R. 5th 357; W. Prosser and W. Page Keeton, *Prosser and Keeton on Torts*, § 104, at 720; e.g., *In re Breast Implant Prod. Liability*, 331 S.C. 540; *Cafazzo*, 542 Pa. 526; *Ayyash*, 533 N.W.2d 353, 210 Mich. App. 142; see *supra* footnote 118 for citations to additional cases from other jurisdictions.

¹⁸¹ This ground for dismissal is discussed in Section I., B., 3. Above.

First, Tennessee law does not allow recovery for losses flowing from personal injury or wrongful death under the TCPA.

Second, Tennessee law does not allow plaintiffs to bring claims concerning the provision of medical services under the TCPA.

1. The TCPA does not provide a remedy for personal injury or wrongful death.

a. The plain language of the TCPA does not provide a remedy for personal injury or wrongful death.

Here, as this Court is well aware, the Plaintiffs claim damages flowing from personal injury or wrongful death.¹⁸²

However, the TCPA only allows plaintiffs to recover actual damages for the “loss of money or property, real, personal, or mixed, or any other article, commodity, or thing of value wherever situated.”¹⁸³ When interpreting a statute, Tennessee courts start with the plain meaning of a statute.¹⁸⁴ If the plain meaning is clear, the court will look no further.¹⁸⁵

Not surprisingly, given the plain language of the statute, Tennessee courts have consistently dismissed claims for losses outside those enumerated in the statute, including claims for damages flowing from personal injury or wrongful death.¹⁸⁶

¹⁸² Master Compl. ¶ 260.

¹⁸³ TENN. CODE. ANN. § 47-18-109(a)(1).

¹⁸⁴ *Waldschmidt v. Reassure Am. Life Ins. Co.*, 271 S.W.3d 173, 176 (Tenn. 2008).

¹⁸⁵ *Green v. Green*, 293 S.W.3d 493, 507 (Tenn. 2009).

¹⁸⁶ *Kirksey v. Overton Pub, Inc.*, 804 S.W.2d 68, 73 (Tenn. Ct. App. 1990); *Akers v. Prime Succession of Tennessee*, 387 S.W.3d 495, 509-10 (Tenn. 2012); *Riddle v. Lowe's Home Ctrs.*, 802 F. Supp. 2d 900, 909 (M.D. Tenn. 2011); *see also Hall v. State*, 137 S.W. 500, 501-02 (Tenn. 1911) (noting that courts should not interpret statutes to create an absurd result).

b. Tennessee courts have consistently interpreted the TCPA as providing a remedy only for losses specifically enumerated in the statute.

In *Kirksey v. Overton Pub, Inc.*¹⁸⁷, the plaintiff parents sued the defendant pub, alleging the pub over-served their son, resulting in a fatal car accident.¹⁸⁸ The plaintiffs attempted to assert a claim under the TCPA.¹⁸⁹ The Tennessee Court of Appeals held that the plaintiff parents could not recover for the wrongful death of their son under the TCPA.¹⁹⁰ In affirming the trial court's dismissal of the plaintiffs' TCPA claim¹⁹¹, the court rejected the argument that the decedent's life was a "thing of value" under the TCPA.¹⁹²

In *Akers v. Prime Succession of Tennessee*¹⁹³, the Tennessee Supreme Court, citing *Kirksey* with approval, held that plaintiffs could not recover under the TCPA for the emotional losses sustained when the defendant mishandled the plaintiffs' son's remains.¹⁹⁴

In *Riddle v. Lowe's Home Centers*¹⁹⁵, the plaintiff brought a personal injury action after being injured while loading plywood into a truck at a Lowe's store.¹⁹⁶ He claimed damages for "serious and disabling personal injuries, which forced him to incur sums of money for medical care, attendance, and lost income," and the plaintiff expected to "continue to incur further medical expenses and losses of income into the future."¹⁹⁷

¹⁸⁷ 804 S.W.2d 68 (Tenn. Ct. App. 1990).

¹⁸⁸ *Id.* at 70.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.* at 73.

¹⁹¹ The trial court struck the plaintiffs' TCPA claims pursuant to Rule 12 of the Tennessee Rules of Civil Procedure, which mirrors its federal counterpart.

¹⁹² *Kirksey*, 804 S.W.2d at 73.

¹⁹³ 387 S.W.3d 495 (Tenn. 2012).

¹⁹⁴ *Id.* at 509-10.

¹⁹⁵ 802 F. Supp. 2d 900 (M.D. Tenn. 2011).

¹⁹⁶ *Id.* at 902.

¹⁹⁷ *Id.* at 908-09.

The District Court for the Middle District of Tennessee¹⁹⁸ granted the defendant's motion to dismiss the plaintiff's TCPA claims because the plaintiff's alleged damages "flow[ed]" from his personal injuries.¹⁹⁹ The court held that "[a] TCPA claim must be dismissed where a plaintiff seeks to recover for injuries to his person resulting from a defendant's alleged violation of the TCPA."^{200 201}

c. The Plaintiffs' claims for damages are not recoverable under the TCPA.

In the Master Complaint, the Plaintiffs allege the following injuries²⁰² resulting from the Tennessee Defendants' alleged violation of the TCPA:

260. Had Clinic Related Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have allowed for the administration of NECC Contaminated Drugs, and would not have incurred related medical costs and injury, and at times, death.²⁰³

Unambiguous Tennessee precedent precludes recovery under the TCPA for (1) losses resulting from wrongful death²⁰⁴ or (2) losses that "flow from" personal injury²⁰⁵.

Therefore, the Court must dismiss the Plaintiffs' TCPA claims.

¹⁹⁸ The Middle District of Tennessee is the district court from which the suits against the Tennessee Defendants were transferred to the MDL.

¹⁹⁹ *Id.* at 909.

²⁰⁰ *Id.* at 909 (internal quotations omitted) (citing *Birdsong v. Eli Lilly*, No. 3-13-01182, 2011 WL 129650, at *3 (M.D. Tenn. Mar. 31, 2011) (dismissing the plaintiff's TCPA claims as they were "specifically link[ed]" to the alleged personal injury)).

²⁰¹ Tennessee's interpretation of its consumer protection statutes with regard to personal injury and wrongful death claims accords with courts in other states. *Howard v. R.J. Reynolds Tobacco Co.*, No. 1:05-cv-27, 2005 WL 2088909, at *3 (E.D. Tenn. Aug. 25, 2005) (citing *Wash. State Phys. Ins. & Ass'n Fisons Corp.*, 858 P.2d 1054, 1060 (Wash. 1993); *Gross-Haentjens v. Leckenby*, 589 P.2d 1209 (Or. Ct. App. 1979). "Those courts which have reached contrary conclusions appear to have done so based upon broader statutory language than that contained in § 47-18-109(a)(1)." *Id.* (citing *Maillet v. ATF-Davidson Co., Inc.* 407 Mass. 185, 552 N.E.2d 95, 99 (Mass. 1990)).

²⁰² The Plaintiffs also claim losses for the monies used to purchase the MPA from the Tennessee Defendants. Master Compl. ¶ 263. However, as discussed in Section II., A. above, health care providers do not sell products used incidental to medical care.

²⁰³ See also, Master Compl. Sec. VII. "Prayer for Relief."

²⁰⁴ *Kirksey*, 804 S.W.2d at 73.

²⁰⁵ *Riddle*, 802 F. Supp. 2d at 909.

2. The TCPA does not provide a remedy for claims related to the provision of medical care.

The Plaintiffs' TCPA claims must also be dismissed because the allegedly unfair or deceptive conduct "concern[s] the actual provision of medical care."²⁰⁶ The TCPA "protect[s] consumers and legitimate business enterprises from those who engage in unfair or deceptive acts or practices in the conduct of any trade or commerce in part or wholly within [Tennessee]."²⁰⁷ But, "[t]he actual practice of medicine does not affect trade or commerce."²⁰⁸

In *Constant v. Wyeth*, the District Court for the Middle District of Tennessee dismissed the plaintiff's TCPA claim against a physician filed in conjunction with her medical malpractice claim.²⁰⁹ The court succinctly noted, "[c]ourts faced with the issue of whether claims of medical malpractice may be brought under a consumer protection statute uniformly have held that they may not because the actual practice of medicine does not affect trade or commerce."²¹⁰ The *Constant* court adopted this reasoning and held that "medical malpractice claims may not be recast as consumer protection act claims."²¹¹

In *Dunlap v. Laurel Manor Health Care, Inc.*²¹², the Tennessee Court of Appeals observed that the administration of medication "directly pertains to medical

²⁰⁶ *Proctor v. Chattanooga Orthopaedic Grp., P.C.*, 270 S.W.3d 56, 59 (Tenn. Ct. App. 2008) (quoting *Constant v. Wyeth*, 352 F. Supp. 2d 847, 853 n. 10 (M.D. Tenn. 2003)).

²⁰⁷ TENN. CODE ANN. § 47-18-102(2).

²⁰⁸ *Constant v. Wyeth*, 352 F. Supp. 2d 847, 853 (M.D. Tenn. 2003) (internal citations omitted).

²⁰⁹ *Id.* at 854.

²¹⁰ *Id.* at 853-54 (citing *Simmons v. Stephenson*, 85 S.W.3d 926, 927-28 (Ky. App. 2002) (collecting cases); *Janusauskas v. Fichman*, 793 A.2d 1109, 1115-16 (Conn. 2002) (collecting cases)).

²¹¹ *Id.* at 854.

²¹² No. E2012-02432-COA-R3-CV, 2013 WL 4680494 (Tenn. Ct. App. Aug. 29, 2013).

treatment.”²¹³ Similarly, the Tennessee Board of Medical Examiners has noted that the administration of medication to patients is a physician’s right.²¹⁴

These authorities support the logical conclusion that a conversation between a physician and patient about a medical procedure pertains to the provision of medical care, not the commercial, entrepreneurial, or business aspects of a health care provider’s medical practice.

The Plaintiffs claim the Tennessee Defendants violated the TCPA by failing to provide the Plaintiffs with enough information regarding the medications used during their epidural steroid injection procedures.²¹⁵ This is an attempt by the Plaintiffs to recast their informed consent claim²¹⁶ as a TCPA claim, which the court in *Constant* specifically rejected.²¹⁷

Logic, precedent, and policy dictate this attempt to plead a health care liability action as a consumer protection action fails as a matter of law. Therefore, consistent with the language of the statute and controlling law, the Court must dismiss the Plaintiffs’ TCPA claims because the allegedly unfair and deceptive conduct concerns the provision of medical care, and the claim and remedy clearly fall outside the substantive scope of the TCPA.²¹⁸

²¹³ *Id.* at *6.

²¹⁴ TENN. COMP. R. & REGS. 0880-2-.14(2)(b)(2).

²¹⁵ Master Compl. ¶ 248 (“Clinic Related Defendants failed to provide accurate disclosures of all material information before Plaintiffs agreed to be injected with an NECC Contaminated Drug”).

²¹⁶ As discussed in Section I., C., 5. above, informed consent claims are governed by Tennessee’s Health Care Liability Act. TENN. CODE. ANN. § 29-26-118.

²¹⁷ *Constant*, 352 F. Supp. 2d at 854.

²¹⁸ *Id.* at 853.

C. The Plaintiffs' claims for medical battery do not state a claim upon which relief can be granted.

As a threshold issue, the Plaintiffs' medical battery claims should be dismissed as they are pled inconsistent with the Health Care Liability Act.²¹⁹

In addition, the Plaintiffs fail to state a claim for medical battery as the Plaintiffs fail to plead that they did not consent to the procedures performed, an essential element of the claim.²²⁰

1. Tennessee law distinguishes between a claim for medical battery and a claim for lack of informed consent.

In Tennessee, for a plaintiff to properly state a claim for medical battery, a plaintiff must allege that he did not consent to the procedure that was performed.²²¹ If a plaintiff admits that the procedure was authorized but alleges the physician failed to disclose the risks of the procedure, the claim is for lack of informed consent.²²²

In Tennessee, "medical battery is a very narrow area of the law."²²³ "The primary consideration in a medical battery case is simply whether the patient knew of and authorized the procedure."²²⁴ The Tennessee Supreme Court articulated the simple inquiry for determining whether a case constitutes medical battery:

(1) was the patient aware that the doctor was going to perform the procedure (i.e., did the patient know that the dentist was going to perform a root canal on a specified tooth or that the doctor was going to perform surgery on the specified knee?); and, if so (2) did the patient authorize performance of the procedure? A

²¹⁹ This ground for dismissal is discussed in Section I., C., 5. above.

²²⁰ *Blanchard v. Kellum*, 975 S.W.2d 522, 524 (Tenn. 1998).

²²¹ *Id.*

²²² *Id.*

²²³ *Moses v. Dirghangi*, No. W2011-02403-COA-R3-CV, 2013 WL 5519506, at *3 (Tenn. Ct. App. Aug. 13, 2013); *Abeyta v. HCA Health Servs. of TN, Inc.*, No. M2011-02254-COA-R3-CV, 2012 WL 5266321, at *9 (Tenn. Ct. App. Sept. 18, 2012).

²²⁴ *Blanchard*, 975 S.W.2d at 524.

plaintiff's cause of action may be classified as a medical battery only when answers to either of the above questions are in the negative.²²⁵

On the other hand, "if the plaintiff is alleging that the doctor failed to inform [the patient] of any or all risks or aspects associated with a procedure, the patient's cause of action rests on an informed consent theory."^{226 227}

In *Moses v. Dirghangi*²²⁸, an analogous case, the plaintiff was admitted at a hospital to give birth.²²⁹ The plaintiff alleged that the defendant physician performed a vaginal exam in a "forceful and abusive manner."²³⁰

Like the Plaintiffs at bar, the *Moses* plaintiff objected to the manner in which the procedure was performed, but she failed to allege that the procedure was performed without her consent.²³¹ The Tennessee Court of Appeals dismissed the medical battery claims for failure to state a claim upon which relief can be granted.²³²

2. The Plaintiffs fail to allege that they did not consent to their procedures, an essential element of a claim for medical battery.

Here, the Plaintiffs characterize their claim as one for medical battery but do not plead the essential elements – (1) that the Plaintiffs did not know the Tennessee Defendants would administer an epidural steroid injection and/or (2) that the Plaintiffs did not authorize the Tennessee Defendants to perform the epidural steroid injection procedure.

The Plaintiffs allege:

²²⁵ *Id.*

²²⁶ *Id.* (emphasis added).

²²⁷ The burden of proof for informed consent claims is stated at Tenn. Code Ann. § 29-26-118 and is discussed in detail in Section I., C., 5. above.

²²⁸ No. W2011-02403-COA-R3-CV; 2013 WL 5579506 (Tenn. Ct. App. Aug. 13, 2013).

²²⁹ *Id.* at *1.

²³⁰ *Id.*

²³¹ *Id.*

²³² *Id.*

297. As part of the medical treatment Plaintiffs received at the Clinic Related Defendants' facilities, their agents and/or employees purchased, prescribed and administered, via injection into the Plaintiffs' bodies NECC Contaminated Drugs which were not sterile and which contained substances, including fungal or bacterial contamination, harmful to human life. Plaintiffs were unaware of the substantial health and safety risk inherent in the use of NECC contaminated Drugs and did not consent to the injection of contaminated drugs into their bodies.²³³

Like the plaintiff in *Moses*, the Plaintiffs here have only alleged that they were not informed of the use of compounded medication prior to the procedure.²³⁴ They have *not* alleged that they did not authorize the *performance of the injection*. In fact, the Plaintiffs affirmatively allege that they *consented* to the procedure: "[m]any, if not all, of the Clinic Related Defendants prepared a Consent for Treatment Form. . . which Plaintiffs read and relied upon when agreeing to accept treatment. . . ."²³⁵

The Plaintiffs fail to plead an indispensable element of their medical battery claim – that they did not consent to the injections. The medical battery claims must be dismissed.

D. The Plaintiffs' claims for lack of informed consent against health care providers, other than the physician who performed the procedure, should be dismissed for failure to state a claim upon which relief can be granted.

Tennessee case law explicitly precludes plaintiffs from making informed consent claims against entities and individuals other than the physician ordering or performing the procedure.²³⁶ Therefore, as a matter of law, the Plaintiffs' lack of informed consent

²³³ Master Compl. ¶ 297 (emphasis added).

²³⁴ *Moses*, No. W2011-02403-COA-R3-CV, 2013 WL 5579506, at *1.

²³⁵ Master Compl. ¶ 302 (emphasis added).

²³⁶ *Bryant v. HCA Health Servs. of Tenn.*, 15 S.W.3d 804, 810 (Tenn. 2000).

claims against STOPNC, Ms. Schamberg, Howell Allen,²³⁷ SSC, and Dr. Lister's Practice should be dismissed for failure to state a claim upon which relief can be granted.

In *Bryant*, the plaintiff underwent two surgeries performed by Dr. McCord at Centennial Medical Center ("Centennial").²³⁸ Prior to Ms. Bryant's surgeries, Dr. McCord provided, and Ms. Bryant signed, consent forms for the surgeries.²³⁹ Dr. McCord performed Ms. Bryant's surgeries at Centennial, and, during both procedures, Dr. McCord inserted pedicle screws into Ms. Bryant's spine.²⁴⁰ At the time of the procedure, the pedicle screws were not approved by the FDA for insertion into the spine.²⁴¹

Ms. Bryant sued Centennial alleging that Centennial: (1) failed to warn her that the FDA had specifically rejected the pedicle screws for implantation in the spine; (2) failed to warn her that the pedicle screws implanted in her spine were experimental; (3) failed to supply the appropriate information to her in obtaining her informed consent; and (4) failed to ensure that Dr. McCord obtained the appropriate informed consent from Ms. Bryant.²⁴²

The Tennessee Supreme Court granted review to determine whether a hospital owes a general duty to obtain the informed consent of a patient undergoing a surgical procedure ordered and performed at the hospital by a non-employee doctor. The court held:

²³⁷ Dr. Culclasure did not perform the injections for some of the Plaintiffs. Accordingly, Dr. Culclasure did not owe a duty to procure the informed consent of the Plaintiffs whose epidural steroid injection procedures he did not perform.

²³⁸ *Bryant*, 15 S.W.3d at 807.

²³⁹ *Id.*

²⁴⁰ *Id.*

²⁴¹ *Id.*

²⁴² *Id.* at 807-08.

We believe that Tenn. Code Ann. § 29-26-118 focuses on the physician ordering the surgical procedure. Mere status as one involved in a patient's care is insufficient to trigger a statutory duty under the informed consent statute. We hold that Tenn. Code Ann. § 29-26-118 generally does not require a hospital to procure a patient's informed consent to surgical procedures ordered and performed by non-employee doctors.²⁴³

Under the clear holding of *Bryant*, STOPNC, Howell Allen, Ms. Schamberg, SSC, and Dr. Lister's Practice (and Dr. Culclasure in cases where he did not perform the procedure) did not owe a duty to obtain the Plaintiffs' informed consent prior to the epidural steroid injections. The Plaintiffs' informed consent claims against STOPNC, Howell Allen, Ms. Schamberg, SSC, and Dr. Lister's Practice (and Dr. Culclasure in cases where he did not perform the procedure) fail to state a claim upon which relief can be granted and must be dismissed.²⁴⁴

E. The Plaintiffs' civil conspiracy claims fail as a matter of law and must be dismissed.

The Plaintiffs irresponsibly allege that the Tennessee Defendants conspired with NECC to fraudulently mislead the Massachusetts Board of Pharmacy.²⁴⁵ However, the Plaintiffs' civil conspiracy claims are (1) barred by the statute of limitations and (2) fail to allege sufficient facts to state a claim upon which relief can be granted and, therefore, should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6).

²⁴³ *Id.* at 810 (emphasis added).

²⁴⁴ Dr. Culclasure did not perform the injections for some of the Plaintiffs. Accordingly, Dr. Culclasure did not owe a duty to procure the informed consent of the Plaintiffs whose epidural steroid injection procedures he did not perform.

²⁴⁵ Master Compl. ¶ 339.

1. The Plaintiffs' claims for civil conspiracy are barred by the statute of limitations.

a. The statute of limitations for a claim of civil conspiracy accrues at the time of the last overt act in furtherance of the conspiracy.

"The limitations period for a civil conspiracy claim commences with the last overt act committed by the co-conspirators in furtherance of the conspiracy."²⁴⁶ "It is the overt act causing the conspiracy that causes the damages and it is from this act that the statute begins to run and not from the suffering or the hurting as a result of the act."²⁴⁷

In Tennessee, the statute of limitations for civil conspiracy claims is determined by the "gravamen of the action."²⁴⁸ Here, the gravamen of the Plaintiffs' civil conspiracy claims is personal injury²⁴⁹, governed by the one-year statute of limitations at Tenn. Code Ann. § 28-3-104.

b. The Plaintiffs' filed their civil conspiracy claims after the expiration of the statute of limitations.

In the case at bar, the last overt acts alleged were the Tennessee Defendants' last orders for medication from NECC.²⁵⁰ STOPNC's last order of MPA from NECC was on or before August 31, 2012, the date of the last shipment of MPA from NECC.²⁵¹ Consequently, the statute of limitations for the Plaintiffs' civil conspiracy claims against STOPNC, Howell Allen, Dr. Culclasure, and Ms. Schamberg expired on August 31, 2013.

²⁴⁶ *Swafford v. Memphis Individual Practice Ass'n*, No. 02A01-9612-CV-00311, 1998 WL 281935, at *12 (Tenn. Ct. App. 1998)

²⁴⁷ *Id.* (quoting *Emerson v. Machamer*, 431 S.W.2d at 283, 286 (Tenn. 1968) (citations omitted)) (emphasis added).

²⁴⁸ *Swafford*, No. 02A01-9612-CV-00311, 1998 WL 281935, at *4; see also *Taylor v. Trans Aero Corp.*, 924 S.W.2d 109, 113 (Tenn. Ct. App. 1995).

²⁴⁹ Master Compl. ¶ 350.

²⁵⁰ Master Compl. ¶ 345.

²⁵¹ Master Compl. ¶ 345.

The Plaintiffs do not allege the shipment dates for SSC, Dr. Lister, and Dr. Lister's Practice in the Master Complaint. However, the Plaintiffs acknowledge that NECC recalled all MPA within the affected lots on September 26, 2012.²⁵² Therefore, applying the facts as alleged in the Master Complaint, the Court can conservatively consider September 26, 2013, as one-year from the last overt act by SSC, Dr. Lister, and Dr. Lister's Practice in furtherance of the alleged conspiracy.²⁵³

Because the Plaintiffs' civil conspiracy claims are barred by the statute of limitations, the Plaintiffs fail to state a claim upon which relief can be granted. Any claims for civil conspiracy against STOPNC, Howell Allen, Dr. Culclasure, and Ms. Schamberg filed after, at the latest, August 31, 2013, are time-barred. Likewise, any claims for civil conspiracy filed after September 26, 2013, against SSC, Dr. Lister, and Dr. Lister's Practice are time-barred.

2. The Plaintiffs fail to allege facts sufficient to sustain claims for civil conspiracy.

a. The Plaintiffs failed to plead the required elements of a civil conspiracy.

The Tennessee Supreme Court defines the tort of civil conspiracy as a "combination of two or more persons who, *each* having the intent and knowledge of the other's intent, accomplish by concert an unlawful purpose, or accomplish a lawful purpose by unlawful means, which results in damage to the plaintiff."²⁵⁴

²⁵² Master Compl. ¶ 64.

²⁵³ The Tennessee Defendants reserve the right to later file a motion for summary judgment with supporting evidence demonstrating that the statute of limitations for civil conspiracy claims against SSC, Dr. Lister, and Dr. Lister's Practice is actually much earlier than September 26, 2013.

²⁵⁴ *Trau-Med of America, Inc. v. Allstate Ins.*, 71 S.W.3d 691, 703 (Tenn. 2002).

Specifically, in the context of an alleged attempt to defraud, as the Plaintiffs at bar have alleged²⁵⁵, the Tennessee Supreme Court has defined civil conspiracy as a “common purpose, supported by a concerted action to defraud, that *each* [conspirator] has the intent to do it, and that it is common to each of them, and that *each* has the understanding that the other has that purpose.”²⁵⁶

Claims for civil conspiracy “must be pled with some degree of specificity,” and “[c]onclusory allegations. . . unsupported by material facts will not be sufficient to state [a claim for civil conspiracy].”²⁵⁷ Failure to state particular and sufficient facts supporting a claim for civil conspiracy mandates dismissal of the plaintiff’s civil conspiracy claim.²⁵⁸

The Plaintiffs allege that the Tennessee Defendants conspired with NECC to violate the rules and regulations of the Massachusetts Board of Pharmacy, specifically “105 CMR § 700.12 [*sic*].”²⁵⁹ The Plaintiffs’ broad allegations clearly fail to meet the specificity requirement for civil conspiracy claims, and thus, the Plaintiffs’ civil conspiracy claims fail to state a claim upon which relief can be granted and must be dismissed.

²⁵⁵ Master Compl. ¶ 338.

²⁵⁶ *Chenault v. Walker*, 36 S.W.3d 45, 52 (Tenn. 2001) (quoting *Dale v. Thomas H. Temple Co.*, 186 Tenn. 69, 90 (1948)) (emphasis added).

²⁵⁷ *Kincaid v. SouthTrust Bank*, 221 S.W.3d 32, 38 (Tenn. Ct. App. 2006) (citing *McGee v. Best*, 106 S.W.3d 48, 64 (Tenn. Ct. App. 2002) (citing *Haynes v. Harris*, No. 01A01-9810-CV-00518, 1999 WL 317946, at *2 (Tenn. Ct. App. 1999) (citations omitted)); see also *In Re Estate of Storey*, No. W2010-00819-COA-R3-CV, 2011 WL 2174901, at *28 (Tenn. Ct. App. Oct. 15, 2010); *O'Dell v. O'Dell*, 303 S.W.3d 694, 697 (Tenn. Ct. App. 2008).

²⁵⁸ See *Kincaid*, 221 S.W.3d at 40; *Beal Bank, SSB v. Prince*, No. M2011-02744-COA-R3-CV, 2013 WL 411452, at *4 (Tenn. Ct. App. Nov. 8, 2012); *In re Estate of Storey*, No. W2010-00819-COA-R3-CV, 2011 WL 2174901, at *29.

²⁵⁹ Master Compl. ¶¶ 338-39.

b. The Plaintiffs fail to specifically plead unlawfulness.

As stated previously, an essential element of a civil conspiracy claim is unlawfulness.²⁶⁰ The Plaintiffs must specifically allege facts to support the allegation that the Tennessee Defendants conspired with NECC to accomplish an unlawful purpose or accomplish a lawful purpose by unlawful means.²⁶¹ The Plaintiffs fail to do so, which is fatal to the claim.

i. 105 CMR § 700.12 does not exist.

The Plaintiffs allege that the Tennessee Defendants conspired with NECC to violate the rules and regulations of the Massachusetts Board of Pharmacy.²⁶² This overbroad accusation that the Tennessee Defendants conspired to break some unknown rule or regulation clearly fails to meet the specific pleading standard for a civil conspiracy claim.

Furthermore, the Plaintiffs specifically pled the Tennessee Defendants conspired with NECC to violate 105 CMR § 700.12.²⁶³ However, this regulation does not exist. Violation of a non-existent regulation obviously cannot meet Tennessee's specific pleading standard for civil conspiracy claims, mandating dismissal.²⁶⁴

²⁶⁰ *Trau-Med*, 71 S.W.3d at 703.

²⁶¹ *Id.*; *Kincaid*, 221 S.W.3d at 38 (citing *McGee v. Best*, 106 S.W.3d 48, 64 (Tenn. Ct. App. 2002) (citing *Haynes v. Harris*, No. 01A01-9810-CV-00518, 1999 WL 317946, at *2 (Tenn. Ct. App. 1999) (internal citations omitted))); see also *In re Estate of Storey*, No. W2010-00819-COA-R3-CV, 2011 WL 2174901, at *28; *O'Dell*, 303 S.W.3d at 697.

²⁶² Master Compl. ¶¶ 338-39.

²⁶³ Master Compl. ¶ 339.

²⁶⁴ *Morris v. Grusin*, No. W2009-00033-COA-R3-CV, 2009 WL 4931324, at *5 (Tenn. Ct. App. Dec. 22, 2009) ("without an unlawful act by the Defendants, [Plaintiffs'] civil conspiracy claim fails."); *Watson's Carpet and Floor Coverings, Inc. v. McCormick*, 247 S.W.3d 169, 186 (Tenn. Ct. App. 2007) ([Defendant] cannot be held liable for helping [alleged co-conspirator] act legally."); see also *Kincaid*, 221 S.W.3d at 39; *Runions v. Tennessee State Univ.*, No. M2008-01574-COA-R3-CV, 2009 WL 1939816 (Tenn. Ct. App. Feb. 17, 2009); *Amodeo v. Conservcare, LLC*, No. W2007-02610-COA-R3-CV, 2009 WL 736656 (Tenn. Ct. App. Oct. 23, 2008).

ii. 105 CMR § 700.012 does not apply because MPA is not a controlled substance as defined by 105 CMR § 700.012.

Assuming that the Plaintiffs meant to cite to 105 CMR § 700.012, the Plaintiffs still do not meet their heightened, “specific” pleading burden, because 105 CMR § 700.012 does not apply to the conduct at issue.

The regulation deals primarily with the creation of a prescription monitoring program.²⁶⁵ Assuming the Plaintiffs intended to allege the Tennessee Defendants conspired with NECC to violate 105 CMR § 700.012(A)(1), the only section arguably applicable, the claims still fail.²⁶⁶ 105 CMR § 700.012(A)(1) requires pharmacies to provide the Massachusetts Department of Health with information about each prescription filled for controlled substances in Schedules II-V and substances classified by the Department as “additional drugs”²⁶⁷. Controlled substances in Schedules II-V are defined by 105 CMR § 700.002(B)-(E), which refers to 21 CFR 1308.12-.15. MPA is not a controlled substance in Schedules II-V. MPA is a prescription drug defined by 105 CMR § 700.002(F) as a Schedule VI controlled substance.

Simply, the Plaintiffs allege a civil conspiracy to violate either a non-existent regulation or a regulation that does not apply to the medication at issue. Because the Plaintiffs do not properly plead a requisite component for a claim of civil conspiracy – unlawfulness – the Plaintiffs fail to state a claim upon which relief can be granted, and the Plaintiffs’ civil conspiracy claims must be dismissed.

²⁶⁵ 105 CMR § 700.012(B)-(F).

²⁶⁶ It is telling that we must guess at what the factual allegations underlying the conspiracy are. That alone should be conclusive of the Plaintiffs’ failure to plead the conspiracy with sufficient specificity.

²⁶⁷ While the Department has the authority to identify “additional drugs,” it does not appear that the Department has invoked that authority for any drug, let alone MPA.

c. The Plaintiffs fail to specifically plead a common purpose to intentionally defraud.

Under Tennessee law, the Plaintiffs also must specifically allege facts supporting a common purpose to intentionally defraud, another essential element.²⁶⁸

The Plaintiffs allege that an NECC representative informed Ms. Schamberg that STOPNC needed to submit a list of patients to NECC with each order to comply with Massachusetts Board of Pharmacy rules and that Ms. Schamberg advised the NECC representative that she could not predict which patients would receive the MPA.²⁶⁹ The NECC representative then allegedly told Ms. Schamberg that a list of previous patient names would suffice.²⁷⁰

Taking the facts as pled, Ms. Schamberg, a Tennessee nurse, accepted the representations of the NECC representative that (1) NECC needed patient names to comply with an unspecified Massachusetts Board of Pharmacy regulation, and (2) a list of previous patient names would satisfy the regulation. The Plaintiffs do not plead that Ms. Schamberg had actual knowledge of Massachusetts Board of Pharmacy regulations, which would be necessary for her to intentionally act to circumvent such regulations.²⁷¹

Because the Plaintiffs do not specifically plead facts supporting a requisite component for a claim of civil conspiracy – common purpose to intentionally defraud –

²⁶⁸ *Chenault*, 36 S.W.3d at 52 (quoting *Dale v. Thomas H. Temple Co.*, 186 Tenn. 69, 90 (1948)); see *Kincaid*, 221 S.W.3d at 38.

²⁶⁹ Master Compl. ¶ 346.

²⁷⁰ Master Compl. ¶ 347.

²⁷¹ No reasonable interpretation of the facts pled would conclude that Ms. Schamberg – a Tennessee nurse – had actual, intricate knowledge of Massachusetts regulations governing prescriptions sufficient to engage in an intentional conspiracy to violate them.

the Plaintiffs fail to state a claim upon which relief can be granted, and the Plaintiffs' civil conspiracy claims must be dismissed.

d. The Plaintiffs fail to specifically plead an injury caused by the alleged civil conspiracy.

In Tennessee, for a valid civil conspiracy claim, the plaintiff must specifically allege that the civil conspiracy caused an injury to the plaintiff.²⁷² The Plaintiffs here have failed to do so.

The Plaintiffs allege that the Tennessee Defendants, in submitting patient names to NECC, violated some unspecified or inapplicable Massachusetts Board of Pharmacy regulation, and that, as a result of NECC receiving patient names in violation of this unknown regulation, the Plaintiffs suffered fungal meningitis and related injuries.²⁷³

Clearly, the Plaintiffs' injuries were not caused by the Tennessee Defendants' submission of allegedly fraudulent patient names to NECC. The Plaintiffs were injured as a result of contamination in the MPA they received. Even if the Tennessee Defendants' had submitted individual, patient-specific prescriptions for each and every vial of MPA purchased from NECC, the prescriptions would not have prevented contamination of the product.

The Plaintiffs fail to specifically plead the requisite causal nexus between the conspiracy and tort, and the claimed injury. Therefore, the Plaintiffs' civil conspiracy claims must be dismissed for failure to state a claim upon which relief can be granted.

²⁷² *Trau-Med.*, 71 S.W.3d at 703.

²⁷³ Master Compl. ¶ 350; Sec. VIII. "Prayer for Relief."

F. The Plaintiffs' claims premised on vicarious liability for the actions of NECC fail as a matter of law because the Plaintiffs do not plead, and cannot plead, sufficient facts to support a finding of an agency relationship.

The Plaintiffs allege that NECC was an agent of the Tennessee Defendants, and therefore, the Tennessee Defendants are vicariously liable for the actions of NECC.²⁷⁴ However, the Plaintiffs fail to plead sufficient facts to establish an agency relationship. Accordingly, the Plaintiffs' agency claims must be dismissed for failure to state a claim upon which relief can be granted.

1. Settled Tennessee law delineates the factors that must exist to establish an agency relationship.

Tennessee courts look to the following factors to determine whether an agency relationship exists:

1. the right to control the conduct of the work,
2. the right of termination,
3. the method of payment,
4. the freedom to select and hire helpers,
5. the furnishing of tools and equipment,
6. the self-scheduling of work hours, and
7. the freedom to render services to other entities.²⁷⁵

The Plaintiffs fail to plead facts sufficient to establish any semblance of an agency relationship. The Master Complaint states that the Tennessee Defendants purchased MPA from NECC, and NECC sold and delivered the MPA to the Tennessee

²⁷⁴ Master Compl. Count X.

²⁷⁵ *McInturff v. Battle Ground Academy of Franklin*, No. M2009-00504-COA-R3-CV, 2009 WL 4878614, at *3 (Tenn. Ct. App. Nov. 5, 2009).

Defendants.²⁷⁶ A sales transaction does not create an agency relationship. No reasonable interpretation of the facts pled could establish that the Tennessee Defendants, as purchasers, were the principal(s) of NECC, the seller.

2. The Plaintiffs fail to allege facts to support any of the seven (7) factors Tennessee courts use to determine whether an agency relationship exists.

The first and principal component in determining whether an agency relationship exists is whether the alleged principal, in this case the Tennessee Defendants, had the right to control the conduct of the agent, NECC.²⁷⁷

The Plaintiffs' solitary allegation related to the Tennessee Defendants' control over NECC is that the Tennessee Defendants "controlled the procurement of drugs from NECC to be sold and administered to their patients."²⁷⁸ Independent choice to select a vendor does not put the purchaser in control of the vendor.²⁷⁹ The Plaintiffs allege no facts to establish that the Tennessee Defendants controlled the conduct of NECC.

Second, the Plaintiffs fail to plead that the Tennessee Defendants hired NECC such that they could have terminated NECC.²⁸⁰ Application of this factor to a buyer-seller relationship is awkward because buyers do not hire and fire sellers in the traditional sense of the words. This awkward application demonstrates the stretch the Plaintiffs are asking the Court to make in finding that an agency relationship existed, or even could have existed, between NECC and the Tennessee Defendants.

²⁷⁶ Master Compl. ¶¶ 330-34.

²⁷⁷ *McInturff*, No. M2009-00504-COA-R3-CV, 2009 WL 4878614, at *3.

²⁷⁸ Master Compl. ¶ 335.

²⁷⁹ The Plaintiffs' absurd interpretation of agency law would make all purchasers responsible for the actions of those from whom they order product. Combined with the Plaintiffs' (incorrect) interpretation of product liability law, the Plaintiffs would be responsible for the actions of the Tennessee Defendants since they allegedly sold medication to the Plaintiffs.

²⁸⁰ *McInturff*, No. M2009-00504-COA-R3-CV, 2009 WL 4878614, at *3.

Third, the Plaintiffs fail to allege any facts regarding the method of payment.²⁸¹ Courts typically gloss over this factor in the agency analysis, but presumably, it pertains to whether the principal takes out payroll taxes, as it would with an employee but not an independent contractor, when paying the agent. As NECC was a vendor and not an employee or independent contractor, this factor also applies awkwardly to the relationship between NECC and the Tennessee Defendants, further demonstrating that no agency relationship existed.

Fourth, the Plaintiffs plead no facts supporting a finding that the Tennessee Defendants controlled NECC's selection and hiring of personnel.²⁸²

Fifth, the Plaintiffs fail to allege any facts demonstrating that the Tennessee Defendants controlled NECC's tools and equipment.²⁸³

Sixth, the Plaintiffs do not allege that the Tennessee Defendants controlled NECC's scheduling of work hours.²⁸⁴

Finally, the Plaintiffs fail to allege that the Tennessee Defendants prohibited NECC from rendering services to other entities.²⁸⁵ In fact, the Plaintiffs affirmatively allege the opposite – that NECC provided MPA to more than 70 hospitals, clinics, health care facilities, and physicians throughout the United States.²⁸⁶

The Plaintiffs fail to allege facts supporting a finding of the presence of even one of the seven (7) factors Tennessee courts look to in determining whether an agency

²⁸¹ *Id.*

²⁸² *Id.*

²⁸³ *Id.*

²⁸⁴ *Id.*

²⁸⁵ *Id.*

²⁸⁶ Master Compl. ¶ 6.

relationship exists. Therefore, the Plaintiffs' absurd claims against the Tennessee Defendants for vicarious liability for the actions of NECC must be dismissed.²⁸⁷

G. The Plaintiffs' claims premised on a breach of a "special duty" fail to state a claim upon which relief can be granted.

While not alleged in the Master Complaint, 66 complaints allege that the Tennessee Defendants breached a "special duty" owed to the Plaintiffs. The Plaintiffs allege that the Tennessee Defendants were in a "special relationship" with their patients, and, as a result of that "special relationship," the Tennessee Defendants owed a duty to protect their patients from the foreseeable intentional actions of NECC, a third party.²⁸⁸

The Plaintiffs' "special duty" claims seek to expand Tennessee law beyond its current bounds. Even if the Court allows this expansion, the Plaintiffs fail to allege the facts necessary to support imposition of joint and several liability, including actual knowledge that NECC would contaminate 17,676 doses of MPA²⁸⁹, and that NECC's actions were intentional. Therefore, the Plaintiffs fail to state a claim upon which relief can be granted, and the Plaintiffs' "special duty" claims should be dismissed.

²⁸⁷ This does not even address the fact that the Plaintiffs apparently allege that NECC's contamination of the medication – and the laundry list of intentional and reckless violations of safety standards they allege – would have to be within the course and scope of the agency to warrant imposition of liability on the principal. Obviously, such conduct would not have been, under any reasonable interpretation of the alleged facts.

²⁸⁸ *Pellicone* Compl. ¶ 195.

²⁸⁹ Master Compl. ¶ 63.

1. Tennessee law does not impose a special duty on a health care provider to protect a patient from the intentional actions of a third party.

The duties owed by a Tennessee health care provider to their patients are codified at Tenn. Code Ann. §§ 29-26-115 and -118.²⁹⁰ Even if the Court accepts that the Plaintiffs can modify an element of proof in the Health Care Liability Act, the Court must still dismiss this claim because Tennessee law does not recognize that health care providers owe a duty to protect their patients from the intentional actions of third parties.

a. The physician-patient relationship does not require physicians to protect patients from the intentional actions of a third party.

In Tennessee, in order to have a “special duty,” there must first be a “special relationship.”²⁹¹ Tennessee limits the special duties arising from the physician-patient relationship to the protection of third parties from the reasonably foreseeable actions of the patient.²⁹² The Plaintiffs seek to have this duty flow in the opposite direction with no support under Tennessee law. Additionally, this line of cases focuses on the physician’s actual knowledge of the threat posed by the patient.²⁹³ Tennessee simply does not impose a duty on a health care provider to protect patients from the intentional actions of third parties.

²⁹⁰ See Section I., C., 2. above.

²⁹¹ See *Bradshaw v. Daniel*, 854 S.W.2d 865, 871 (Tenn. 1993).

²⁹² *Id.*

²⁹³ See *Burroughs v. Magee*, 118 S.W.3d 323, 329-30 (Tenn. 2003) (summarizing Tennessee case law regarding the physician-patient special duty).

b. This Court should abstain from expanding Tennessee law to create a duty for physicians to protect patients from the intentional and reasonably foreseeable actions of a third party.

Ad hoc expansion of legal responsibility for health care providers to include a duty to prevent intentional, even criminal, acts of third parties is senseless. Simple, altogether common, examples demonstrate this point.

Under the Plaintiffs' theory, if a physician was aware, or should have been aware, of increasing armed robberies in a patient's neighborhood but did not protect the patient from being mugged, the physician would be jointly and severally liable with the mugger for the theft of the patient's belongings, and any accompanying personal injury.

Directly pertinent to the pending action, clear public policy reflects the decision to place the duty to protect patients from the intentional acts of manufacturers of pharmaceuticals with the federal Food and Drug Administration ("FDA"), not individual physicians, clinics, and hospitals. The FDA acknowledges this duty:

FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.²⁹⁴

Because (1) the duties owed by a Tennessee health care provider to their patients are codified at Tenn. Code Ann. §§ 29-26-115 and -118, and (2) Tennessee common law does not impose a duty on physicians to protect their patients from the intentional actions of third parties, the Plaintiffs' "special duty" claims must be dismissed.

²⁹⁴ <http://www.fda.gov/aboutfda/whatwedo/default.htm>

2. To the extent the Court finds a “special duty” does exist, the Plaintiffs fail to plead facts supporting the imposition of joint and several liability.

If the Court allows the Plaintiffs’ expansion of Tennessee law in finding a “special duty” exists, the Plaintiffs also fail to plead facts supporting the imposition of joint and several liability for the injuries resulting from breach of that duty.

As a consequence of the alleged breach of this “special duty,” the Plaintiffs allege that the Tennessee Defendants are jointly and severally liable with NECC.²⁹⁵ Tennessee is a comparative fault state, and strongly disfavors joint and several liability.²⁹⁶

Presumably, the Plaintiffs rely on *Limbaugh v. Coffee Med. Ctr.*²⁹⁷ for the proposition that the Tennessee Defendants are jointly and severally liable with NECC. However, the facts of that case are entirely inapposite to the case at bar.

In *Limbaugh*, the Tennessee Supreme Court held that a retirement facility owed a duty to protect its residents from the reasonably foreseeable intentional actions of *the facility’s employee*, a nurse.²⁹⁸ The facility had timely and explicit knowledge that the nurse had a propensity for anger.²⁹⁹ Eighteen days prior to attacking the plaintiff, the nurse attacked a resident’s family member in an altercation that was witnessed by several other employees and was reported to the Director of Nursing and the

²⁹⁵ *Pellicone Compl.* ¶ 199.

²⁹⁶ See *McIntyre v. Balentine*, 833 S.W.2d 52, 58 (Tenn. 1992) (“it would be inconsistent to simultaneously retain a rule, joint and several liability, which may fortuitously impose a degree of liability that is out of all proportion to fault.”); see also TENN. CODE ANN. § 29-11-107 (further eliminating common law joint and several liability).

²⁹⁷ 59 S.W.3d 73 (Tenn. 2001).

²⁹⁸ *Id.* at 76.

²⁹⁹ *Id.* at 77.

Administrator of the facility.³⁰⁰ The facility took no action against its employee-nurse before she assaulted the plaintiff.³⁰¹ Under these facts, the facility argued that its negligence should be comparably mitigated by the nurse's intentional assault and battery.³⁰²

The Tennessee Supreme Court ruled that when a retirement facility "voluntarily assumes an obligation to provide care for those who are unable because of physical or mental impairment to provide care for themselves,"³⁰³ the facility's negligence cannot be comparably mitigated by the intentional actions *of its employee*.³⁰⁴ The court stated, "we conclude that where the harm arising from the intentional acts of the nursing assistant was a foreseeable risk created by the negligent medical center, and all tortfeasors have been made parties to the suit, each tortfeasor party shall be held jointly and severally liable for the entire amount of damages awarded."^{305 306}

A similar imposition of joint and several liability is inappropriate in the case at bar. Unlike *Limbaugh*, the alleged intentional actor is not an employee of the Tennessee Defendants. And, the allegedly foreseeable risk was not created by the Tennessee Defendants, it was created by NECC. Additionally, the Plaintiffs here were not under the protection of the Defendants due to physical or mental impairments. Finally, the Plaintiffs do not allege the Tennessee Defendants had actual notice that NECC would intentionally contaminate the MPA.

³⁰⁰ *Id.*

³⁰¹ *Id.*

³⁰² *Id.* at 86-87.

³⁰³ *Id.* at 79-80 (internal citations and quotation marks omitted).

³⁰⁴ *Id.* at 86-87.

³⁰⁵ *Id.* at 76 (emphasis added).

³⁰⁶ The Tennessee legislature has since abolished the imposition of *Limbaugh* joint and several liability for all cases accruing after July 1, 2013, pursuant to Tenn. Code Ann. § 29-11-107.

Put simply, no Tennessee statute or case law applied to the facts as pled supports a claim for relief based on violation of some novel “special duty” owed to the Plaintiffs. Therefore, the Plaintiffs’ “special duty” claims must be dismissed.

CONCLUSION

The wrongdoer here – NECC – has reportedly resolved the claims against it for a sum exceeding \$100 million.³⁰⁷ Predictable efforts to corral other solvent parties, including health care providers in Tennessee, simply do not clear the legal hurdles required to sustain the asserted claims for relief.

Health Care Liability Act

The Plaintiffs – creatively – try to disguise this statutorily-defined “health care liability action” as various other causes of action, presumably in an attempt to avoid the pre-suit and proof requirements of the Health Care Liability Act. The Plaintiffs cannot do so. The facts of the complaints allege injury related to the provision of health care services. Thus, the Health Care Liability Act controls these complaints.

The complaints that do not comply with the pre-suit notice and certificate of good faith requirements must be dismissed. In addition, the causes of action inconsistent with the burden of proof and elements of a health care liability action must also be dismissed.

Product Liability

Tennessee health care providers administering injectable medication during a procedure are not *sellers* of that medication such that they must insure its safety.

³⁰⁷ See Wallack, Tom, *Framingham compounding pharmacy owners, insurers tentatively agree to contribute more than \$100m to fund for victims, creditors*, BOSTON GLOBE, Dec. 23, 2013 available at <http://www.boston.com/news/local/massachusetts/2013/12/23/meningitis/o5e3zbofITVcicPdDvgfpl/story.html>

Imposition of strict legal liability is contrary to controlling Tennessee law, the overwhelming law in this country, the consensus of tort commentators, and sound public policy.

Tennessee Consumer Protection Act

The TCPA does not provide an avenue of recovery for personal injury or wrongful death. Tennessee courts have consistently rebuffed attempts to misuse the TCPA to recover in personal injury and medical malpractice actions.

Ordinary Negligence

The Health Care Liability Act eliminated ordinary negligence claims against health care providers related to the provision of health care services.

Medical Battery

The Plaintiffs do not allege the required element of a medical battery claim – that the patient did not authorize the procedure. In fact, the Plaintiffs allege the opposite – that they consented to the procedures. A medical battery claim under Tennessee law fails.

Informed Consent

Any claim for lack of adequate disclosure of risks must be brought pursuant to Tenn. Code Ann. § 29-26-118. Tennessee does not permit claims for lack of informed consent against anyone other than the physician recommending and performing the procedure. Thus, any claim not brought consistent with Tenn. Code Ann. § 29-26-118 and/or against persons or entities not performing the procedure must be dismissed.

Civil Conspiracy

The claims for civil conspiracy brought beyond the one-year anniversary of the last overt act in furtherance of the conspiracy are time-barred. In addition, the claims fail to specifically plead facts to sustain the essential elements of the claim, namely the unlawfulness of the conspiracy, and the requisite knowledge and intent.

Vicarious Liability

The Plaintiffs do not plead any facts to support the notion that the Tennessee Defendants controlled the actions of NECC. The vicarious liability claim should be dismissed.

“Special Duty”

Tennessee law does not impose a “special duty” on physicians to protect patients from the intentional acts of third parties. This Court, respectfully, should not create one.

REQUEST FOR RELIEF

Thus, these Tennessee Defendants respectfully request an order finding:

1. The Tennessee Health Care Liability Act controls this health care liability action
2. Any complaints that fail to comply with the pre-suit notice and/or certificate of good faith requirements of § 29-26-121 and/or § 29-26-122 are dismissed
3. The Plaintiffs' product liability claims are dismissed because they are contrary to the Tennessee Health Care Liability Act and/or Tennessee law does not recognize a cause of action against health care providers for product liability where the providers employ the product incidental to an individual's medical care
4. The Plaintiffs' TCPA claims are dismissed because the TCPA does not provide a remedy in personal injury and health care liability cases
5. The Plaintiffs' ordinary negligence claims are dismissed because they fail to allege a violation of the recognized standard of acceptable professional practice.
6. The Plaintiffs' medical battery claims are dismissed because the Plaintiffs fail to plead that they did not authorize the procedures, a required element of a Tennessee medical battery claim
7. The Plaintiffs' informed consent claims must be brought pursuant to Tenn. Code Ann. § 29-26-118 and can only be sustained against the physician recommending and performing the procedure
8. The Plaintiffs' civil conspiracy claims are dismissed as time-barred and/or for failure to specifically plead facts necessary to establish the elements of the claims
9. The Plaintiffs' vicarious liability claims are dismissed for failure to plead facts to establish that NECC was acting as an agent of the Tennessee Defendants
10. The Plaintiffs' "special duty" claims are dismissed because Tennessee law does not recognize such a claim based on the facts pled in the complaints.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 10th day of January, 2013.

/s/ Chris Tardio

Chris Tardio